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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

Date: December 20, 2005

Subject: Dicamba. Residue Chemistry Considerations for the Reregistration Eligibility Decision (RED) Document. Summary of Analytical Chemistry and Residue Data.

DP Number: D317699
Decision Number: 357484
Chemical Class: Benzoic acid herbicide
40 CFR §180: 227
PC Codes: 029801 - Dicamba acid
029802 - Dimethylamine (DMA) salt of dicamba
029806 - Sodium (Na) salt of dicamba
128931 - Diglycolamine (DGA) salt of dicamba
128944 - Isopropylamine (IPA) salt of dicamba
129043 - Potassium (K) salt of dicamba

From: Christine L, Olinger, Chemist
Reregistration Branch I
Health Effects Division (7509C)

Through: Whang Phang, Ph.D., Branch Senior Scientist
Reregistration Branch I
Health Effects Division (7509C)

Chemistry Science Advisory Council
Health Effects Division (7509C)

To: Kendra Tyler, CRM
Reregistration Branch I
Special Review and Reregistration Division (7508C)

This document was originally prepared under contract by Dynamac Corporation (20440 Century Boulevard, Suite 100; Germantown, MD 20874; submitted 06/16/2005). The document has been reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

DEC 21 2005

Executive Summary

Dicamba (3,6-dichloro-2-methoxybenzoic acid is a selective benzoic acid herbicide registered for the control of weeds prior to their emergence. Different forms of dicamba (acid and salt) have registered uses on several food/feed crops including asparagus, barley, corn (field and pop), grasses grown in pasture and rangeland, oats, proso millet, rye, sorghum, soybeans, sugarcane, and wheat. Application rates range from 0.5 to 2.8 lb ae/A.

The Agency's Special Review and Reregistration Division (SRRD) issued a Use Closure Memorandum for Dicamba (Case No. 0065) on 8/2/05 in an attempt to provide use information that will be incorporated into the preliminary risk assessment for dicamba. The registrants intend to support all currently registered uses described in the Use Closure Memo and all currently registered products. The different forms of dicamba acid and salts that will be supported for reregistration, include: the dicamba acid (PC Code 029801), dimethylamine (DMA) salt (PC Code 029802), sodium (Na) salt (PC Code 029806), isopropylamine (IPA) salt (PC Code 128944), diglycolamine (DGA) salt (PC Code 128931), and potassium (K) salt (PC Code 129043).

The nature of the residue in plants is adequately understood based on the aggregate of metabolism studies conducted on several crops. The results of these studies indicate that dicamba is rapidly absorbed and translocated by grasses, grapes, black valentine beans, wheat, bluegrass, and soybeans. It is also rapidly absorbed by sugarcane following foliar application but it is very slowly translocated from the leaves to the roots. The metabolism of dicamba in plants proceeds mainly by demethylation and hydroxylation.

The residues of concern in barley, corn, cotton, grasses, oat, proso millet, sorghum, sugarcane, and wheat are dicamba and its 3,6-dichloro-5-hydroxybenzoic acid (5-OH dicamba) metabolite; these are the residues currently regulated in 40 CFR §180.227 (a)(1). In asparagus, the residues of concern are dicamba and its 3,6-dichloro-2-hydroxybenzoic acid metabolite [40 CFR §180.227 (a)(2)]; the metabolite 3,6-dichloro-2-hydroxybenzoic acid is also referred to as 3,6-dichlorosalicylic acid (DCSA). The residues of concern in/on aspirated grain fractions and soybeans are dicamba, 5-OH dicamba, and DCSA [40 CFR §180.227 (a)(3)]. The current tolerance definitions are appropriate for all crop commodities with registered uses.

The nature of the residue in animals is adequately understood based on acceptable metabolism studies conducted on ruminants and poultry. The compounds identified in these studies include dicamba, DCSA, and 2-amino-3,6-dichlorophenol. The latter compound was identified only in hen liver at <1% of total radioactive residues and thus, need not be included in the tolerance expression. The residues of concern in meat, milk, poultry and eggs remain unchanged and consist of dicamba and 3,6-dichloro-2-hydroxybenzoic acid [40 CFR §180.227 (a)(2)].

The nature of the residue in rotational crops is understood. The results of an acceptable confined rotational crop study showed that at a plantback interval of 120 days, the total radioactive residues were <0.01 ppm in/on samples of collard greens (a representative of leafy vegetables) and carrots (a representative of root crops) but were >0.01 ppm in the matrices of barley (a representative of small grains). Residue characterization of barley matrices from the 120-day rotation showed that a substantial percentage of TRR was associated with natural plant constituents (lignin and cellulose).

Limited and/or extensive field accumulation studies with dicamba need not be conducted and rotational crop tolerances need not be established *provided* the registrants are willing to amend all dicamba labels to specify a 120-day plantback interval when dicamba is applied at a maximum seasonal rate of 0.75 lb ae/A or less. At application rates of 0.75-2.0 lb ae/A, the labels should specify that only crops with established tolerances can be rotated.

There are adequate plant enforcement methods. The Pesticide Analytical Manual (PAM) Vol. II lists Method I (AM 0268A), a GC method with electron capture detection (GC/ECD) for the enforcement of dicamba plant tolerances. The sensitivity of the method is listed at 0.05 ppm. An improved plant enforcement method (GC/ECD) has resulted from the requirements of the 6/30/89 Residue Chemistry Chapter of the Dicamba (SRR). The Chapter requested that Method AM-0691A or B, both of which were modifications to Method I of PAM Vol. II (AM 0268A), be subjected to an independent laboratory validation (ILV) because the method procedures included an acid hydrolysis step which increased the extraction efficiency of dicamba residues from various commodities. Method AM-0691B-0593-2 has been subjected to a successful ILV as well as EPA method validation. Pending a re-write of the method to incorporate suggested changes/corrections made by Agency chemists from ACL, the method will be forwarded to FDA for publication in PAM Vol. II. It is noted that Methods AM-0691B-0593-2 and -3 were recently superceded by Method AM-0691B-0297-4, which consists of a more detailed step-by-step description of the procedures, GC-MS confirmatory tests, and additional recovery data. The LOQ for dicamba and 5-OH dicamba is 0.02 ppm.

Several data-collection methods were used for the analysis of samples, collected from recent field and processing studies. In essence, these data-collection methods were based on or modifications of the improved enforcement method. In conjunction with PP#4F3041, additional method validation data using Method AM-0691B-0297-4 are required for barley grain and straw at fortification levels of 6 and 15 ppm, respectively, and for wheat straw at 30 ppm because the maximum residues obtained from the respective field trials were not validated at these levels. In addition, the registrants are required to submit additional method validation data using Method AM-0941-1094-0 for soybean seeds at a spike level of 10 ppm. The registrants have committed to generate these data.

For the enforcement of animal commodity tolerances, PAM Vol. II lists Method II, a GC/ECD method which is identical to Method I. The sensitivity of the method is listed at 0.01 ppm. Based on the results of animal metabolism study, which showed that acid hydrolysis can additionally extract up to 30% of TRR in goat liver, HED is requiring the registrants to revise/improve Method II to include an acid hydrolysis step and submit additional validation data. Method II should also be re-written specifically for the analysis of the parent dicamba and its metabolite 3,6-dichloro-2-hydroxybenzoic acid metabolite in animal matrices.

According to FDA's PAM Volume I, Appendix II, dicamba is completely recovered using Section 402 E2 of Protocol B but is only partially recovered using Section 402 E1 of Protocol B. There are no multiresidue methods recovery data for the dicamba metabolites of concern (5-OH dicamba and DCSA), and these data are required.

There are adequate storage stability data for a wide variety of crop commodities except on sugarcane molasses. Storage stability data are required for sugarcane molasses to validate the interval and conditions of samples collected from the submitted sugarcane processing study (MRID 43245204). The available storage stability data indicate that residues of dicamba and its metabolites are reasonably stable under frozen storage conditions in/on: (i) field corn forage, silage, grain, and fodder for up to 3 years (dicamba) and 2 years (5-OH dicamba); (ii) soybean forage for up to 4 months and in refined oil for up to 3 months; (iii) grass forage and hay for up to 314 and 320 days, respectively; (iv) asparagus for up to 104 days (dicamba and DCSA) and 119 days (5-OH dicamba); and (iv) refined white sugar of sugarcane for up to 60 days.

The available storage stability data (MRID 46668101) for animal commodities indicate dicamba and its metabolite 3,6-dichloro-2-hydroxybenzoic acid are stable in ruminant muscle, fat, kidney, liver, and milk for at least 18 months. No additional storage stability data are required to support the existing livestock feeding studies.

Ruminant feeding studies have been conducted at the feeding levels of 400 and 1000 ppm dicamba. Based on a review of the 1000 ppm study (MRID 44891303) and an estimated maximum theoretical dietary burden of 482 ppm, tolerances for livestock commodities require revision, ranging from a level of 0.25 ppm for meat to 25 ppm for kidney.

A poultry feeding study with dicamba is not required based on the results of the submitted poultry metabolism study. In the poultry study, the TRR levels in eggs, liver, muscle, and fat were all <0.004 ppm following dosing at 10 ppm (~1.9x the maximum dietary burden of 5.2 ppm) in the diet for four consecutive days. Residues in eggs plateaued after the first day of dosing (i.e., there was no accumulation with increasing days of dosing). HED does not anticipate the occurrence of quantifiable residues of dicamba or DCSA in poultry eggs and meat as a result of treating crops that are poultry feed items at the maximum use patterns. Therefore, HED concludes that tolerances are not needed in poultry eggs and meat at this time but may be required if additional uses are registered in the future.

Residue studies that were generated by Craven Laboratories had been identified by HED, and a Data Call-In Notice was issued on 02/94 requesting end-use producer(s) of dicamba to conduct new field trials on barley, corn (field), sorghum, soybean, sugarcane, and wheat. Several residue chemistry studies have been submitted and reviewed in response to the Dicamba DCI Notice. These Craven-replacement data along with data submitted for the remainder of crops listed in the Dicamba Master Use Profile were re-evaluated in this Residue Chemistry Chapter. Listed below are HED's findings.

Pending label revisions and/or adjustment of tolerances for some commodities, there are adequate residue data to fulfill reregistration requirements for: asparagus; grass forage and hay; sorghum grain, forage, and stover; and soybean seed and hulls.

It is the current Agency policy to allow label restrictions on the feeding/grazing of livestock animals on soybean forage and hay, thus, precluding the need for residue data and tolerances for these soybean commodities. HED defers to RD for verifying whether such restrictions exist on product labels. If such restrictions appear on the labels, then residue data and tolerances for soybean forage and hay are not necessary. If no such restrictions appear on the labels, then the registrants are required to propose tolerances for soybean forage and hay; based on the available data, a tolerance level of 0.1 ppm would be appropriate for each soybean commodity. Concomitant with these tolerance proposals, the registrants are required to propose a maximum seasonal rate of 0.5 lb ae/A for preplant application on soybean grown for forage and hay only.

The submitted data for several crop commodities are inadequate because they do not reflect the maximum use rates listed in Dicamba Master Use Profile. To fulfill reregistration requirements, the registrants are required to submit additional data for the following commodities: barley, grain, hay, and straw; corn, field, grain, forage, and stover; cotton gin by-products; sugarcane; and wheat grain and straw. In lieu of submitting additional data for the above-listed commodities, the registrants are given the option to rely on the available data provided they revise their product labels for consistency with the reviewed data.

There are adequate residue data on the aspirated grain fractions of sorghum, soybean, and wheat. Although the available data support the current tolerance level of 5100 ppm, additional data are required for the aspirated grain fractions of field corn since an examination of BEAD Use Pattern Table indicates that various salt formulations of dicamba may be applied early and late postemergence to the crop.

HED will allow the translation of available/requested field trial data from some crop commodities to agronomically related commodities with identical uses. The available/requested data for field corn grain and stover may be translated to pop corn grain and stover. The available/requested data for wheat grain, forage, hay, and straw may be translated to the respective commodities of proso millet, oat, and rye. Where translation of data is allowed, any HED recommendations with regards to label revisions as well as tolerance reassessment should apply to all respective crop commodities.

The Agency no longer considers sugarcane forage and fodder to be significant livestock feed items, and these items have been deleted from Table 1 of OPPTS 860.1000. Therefore, the established tolerances for sugarcane forage and fodder should be revoked.

There are acceptable processing studies with dicamba on corn, soybean, sugarcane, and wheat. The soybean processing study resulted in a processing factor of 3.8x for residues of dicamba in soybean hulls but no concentration of residues was observed in other soybean fractions (meal, crude oil and refined oil). The sugarcane processing study showed that the combined residues were nondetectable (<0.01 ppm) in refined sugar but concentrated in molasses (processing factor of 24.4x). The combined residues in soybean hull and sugarcane molasses are expected to exceed the respective established tolerances when the maximum highest average field trial (HAFT) residues are multiplied by the processing factor; HED is therefore, recommending an upward adjustment to the tolerances. The wheat processing study showed that the combined residues of dicamba and 5-OH dicamba did not concentrate in any wheat processed fractions.

A corn processing study indicates that dicamba residues do not concentrate in corn processed products. The available wheat grain processing data may be translated to barley and oats. A millet grain processing study is not required since the only processed commodity associated with millet is flour. Endnote 44 of Table 1 OPPTS 860.1000 specifies that millet flour is not produced significantly in the U.S. for human consumption, and residue data are not needed at this time. A sorghum processing study is not required since sorghum flour is used in the U.S. exclusively for drywall, and not as a human food or a feedstuff.

Regulatory Recommendations and Residue Chemistry Deficiencies

Listed below is a summary of residue chemistry data deficiencies that must be fulfilled for reregistration. A human health risk assessment is forthcoming.

- Additional method validation data using Method AM-0691B-0297-4; recovery data are needed for barley grain and straw at fortification levels of 6 and 15 ppm, respectively, and for wheat straw at 30 ppm. Additional method validation data using Method AM-0941-1094-0 are also needed for soybean seeds at a spike level of 10 ppm.

- Revise/improve Method II of PAM Vol. II to include an acid hydrolysis step and submit additional validation data. Method II should also be re-written specifically for the analysis of the parent dicamba and its metabolite 3,6-dichloro-2-hydroxybenzoic acid metabolite in animal matrices.

- Multiresidue methods recovery data for the dicamba metabolites of concern (5-OH dicamba and DCSA).

- Storage stability data for sugarcane molasses.

- Residue data and tolerances for soybean forage and hay if no feeding restrictions appear on the label.

- Additional information on the crop field trial study for cotton gin by-products (MRID 45196801).

- Magnitude of the residue data for the following commodities: barley, grain, hay, and straw; corn, field, grain, forage, and stover; sugarcane; and wheat grain and straw. In lieu of submitting additional data for the above-listed commodities, the registrants have the option of relying on the available/submitted data provided they revise their product labels for consistency with the reviewed data.

Background

Identification of Active Ingredient

The PC code and nomenclature of dicamba and its salts are presented in Table 1. The physicochemical properties of dicamba and its salts are listed in Table 2. PC Codes 029803, 029804, and 029807 are no longer being supported and have been canceled; these dicamba salts are not included in Tables 1 and 2.

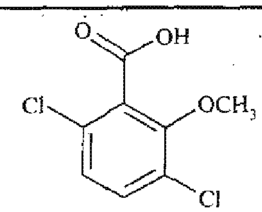
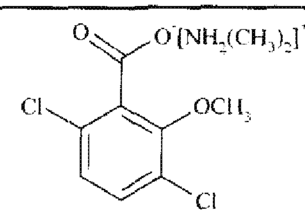
Table 1. Dicamba and its Salts Nomenclature	
PC Code 029801	
Chemical structure	
Common name	Dicamba acid
Molecular Formula	$C_8H_6Cl_2O_3$
Molecular Weight	221.04
IUPAC name	3,6-dichloro-*o*-anisic acid
CAS name	3,6-dichloro-2-methoxybenzoic acid or 2-methoxy-3,6-dichlorobenzoic acid
CAS #	1918-00-9
PC Code 029802	
Chemical structure	
Common name	Dicamba dimethylamine salt (DMA salt)
Molecular Formula	$C_{10}H_{13}Cl_2NO_3$
Molecular Weight	266.1
CAS #	2300-66-5
PC Code 029806	

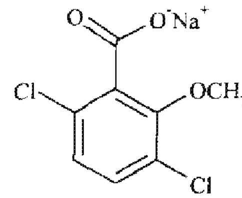
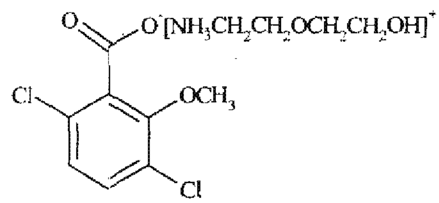
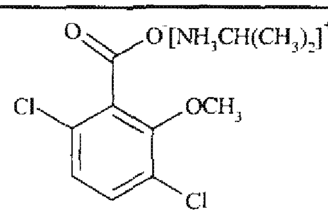
Table 1. Dicamba and its Salts Nomenclature	
Chemical structure	
Common name	Dicamba sodium salt (Na salt)
Molecular Formula	$C_8H_5Cl_2NaO_3$
Molecular Weight	243.0
CAS #	1982-69-0
PC Code 128931	
Chemical structure	
Common name	Dicamba diglycolamine salt (DGA salt)
Molecular Formula	$C_{12}H_{17}Cl_2NO_5$
Molecular Weight	326.18
CAS #	104040-79-1
PC Code 128944	
Chemical structure	
Common name	Dicamba isopropylamine salt (IPA salt)
Molecular Formula	$C_{11}H_{15}Cl_2NO_3$
Molecular Weight	280.15
CAS #	55871-02-8

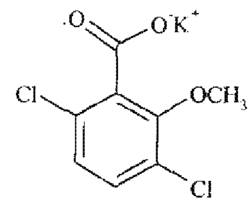
Table 1. Dicamba and its Salts Nomenclature	
PC Code 129043	
Chemical structure	
Common name	Dicamba potassium salt (K salt)
Molecular Formula	$C_8H_5Cl_2KO_3$
Molecular Weight	259.1
CAS #	10007-85-9

Table 2. Physicochemical Properties of Dicamba and its Salts		
Parameter	Value	Reference
Dicamba acid (PC Code 029801)		
Melting point	114-116 °C (PAI) 90-100 °C (87% TGAI)	SRR Reregistration Standard, 6/30/89
pH	2.5-3.0 (87% TGAI)	
Density, bulk density, or specific gravity	1.57 g/mL at 25 °C (87% TGAI)	
Water solubility	0.5 g/100 mL at 25 °C (PAI)	
Solvent solubility	g/100 mL at 25 °C (PAI) dioxane 118.0 ethanol 92.2 isopropyl alcohol 76.0 methylene chloride 26.0 acetone 17.0 toluene 13.0 xylene 7.8 heavy aromatic naphthalene 5.2	
Vapor pressure	3.4×10^{-5} mm Hg at 25 °C (PAI)	
Dissociation constant, pK_a	1.97 (PAI)	
Octanol/water partition coefficient	0.1 (PAI)	
UV/visible absorption spectrum	neutral: 511 (275 nm) acidic (pH 0-1): 1053 (281 nm) basic (pH 13-14): 469 (274 nm)	RD D266167, 6/26/00, B. Kitchens

Table 2. Physicochemical Properties of Dicamba and its Salts

Parameter	Value	Reference
Dicamba DMA salt (PC Code 029802)		
Melting point	101.0-114.5 °C	D213276, D216855, D216859, D216853, D216857, D216862, D217061, D218789, D218792, D218784, D218787, and D218786, 11/21/95, L. Cheng
pH	3.89 at 25 °C (1% solution)	
Density, bulk density, or specific gravity	0.77 g/mL at 25 °C (tap density)	
Water solubility	94.5 g/100 mL at 25 °C	
Solvent solubility	N/A; data for the free acid are representative of the dicamba salts	D198000, 5/5/94, P. Deschamp
Vapor pressure		
Dissociation constant, pK_a		
Octanol/water partition coefficient	$K_{OW} = 0.078$	D213276, D216855, D216859, D216853, D216857, D216862, D217061, D218789, D218792, D218784, D218787, and D218786, 11/21/95, L. Cheng
UV/visible absorption spectrum	Not available	
Dicamba Na salt (PC Code 029806)		
Melting point	320-325 °C	RD Memorandum, 9/26/94, T. Alston
pH	7.16	
Density, bulk density, or specific gravity	1.03 g/mL at 25 °C	
Water solubility	N/A; data for the organic salts (DMA, DGA, and IPA) are representative of the Na salt	D198000, 5/5/94, P. Deschamp
Solvent solubility	N/A; data for the free acid are representative of the dicamba salts	
Vapor pressure		
Dissociation constant, pK_a		
Octanol/water partition coefficient	N/A; data for the organic salts (DMA, DGA, and IPA) are representative of the Na salt	
UV/visible absorption spectrum	Not available	
Dicamba DGA salt (PC Code 128931)		
Melting point	52.0-85.0 °C	D213276, D216855, D216859, D216853, D216857, D216862, D217061, D218789, D218792, D218784, D218787, and D218786, 11/21/95, L. Cheng
pH	7.60 at 25 °C (1% solution)	
Density, bulk density, or specific gravity	0.69 g/mL at 25 °C (tap density)	
Water solubility	107 g/100 mL at 25 °C	

Table 2. Physicochemical Properties of Dicamba and its Salts		
Parameter	Value	Reference
Solvent solubility	N/A; data for the free acid are representative of the dicamba salts	D198000, 5/5/94, P. Deschamp
Vapor pressure		
Dissociation constant, pK_a		
Octanol/water partition coefficient	$K_{OW} = 0.061$	D213276, D216855, D216859, D216853, D216857, D216862, D217061, D218789, D218792, D218784, D218787, and D218786, 11/21/95, L. Cheng
UV/visible absorption spectrum	Not available	
Dicamba IPA salt (PC Code 128944)		
Melting point	93.5-127.5 °C	D213276, D216855, D216859, D216853, D216857, D216862, D217061, D218789, D218792, D218784, D218787, and D218786, 11/21/95, L. Cheng
pH	4.68 at 25 °C (1% solution)	
Density, bulk density, or specific gravity	0.63 g/mL at 25 °C (tap density)	
Water solubility	59.6 g/100 mL at 25 °C	
Solvent solubility	N/A; data for the free acid are representative of the dicamba salts	D198000, 5/5/94, P. Deschamp
Vapor pressure		
Dissociation constant, pK_a		
Octanol/water partition coefficient	$K_{OW} = 0.070$	D213276, D216855, D216859, D216853, D216857, D216862, D217061, D218789, D218792, D218784, D218787, and D218786, 11/21/95, L. Cheng
UV/visible absorption spectrum	Not available	
Dicamba K salt (PC Code 129043)		
Melting point	Decomposes at 213.5 °C	D213276, D216855, D216859, D216853, D216857, D216862, D217061, D218789, D218792, D218784, D218787, and D218786, 11/21/95, L. Cheng
pH	8.12 at 25 °C (1% solution)	
Density, bulk density, or specific gravity	0.88 g/mL at 25 °C (tap density)	
Water solubility	N/A; data for the organic salts (DMA, DGA, and IPA) are representative of the K salt	D198000, 5/5/94, P. Deschamp
Solvent solubility	N/A; data for the free acid are representative of the dicamba salts	
Vapor pressure		
Dissociation constant, pK_a		
Octanol/water partition coefficient	N/A; data for the organic salts (DMA, DGA, and IPA) are representative of the K salt	

Table 2. Physicochemical Properties of Dicamba and its Salts		
Parameter	Value	Reference
UV/visible absorption spectrum	Not available	

860.1200 Directions for Use

Product List: The different forms of dicamba acid and salts with food/feed uses, that will be supported for reregistration, include: the dicamba acid (PC Code 029801), dimethylamine (DMA) salt (PC Code 029802), sodium (Na) salt (PC Code 029806), isopropylamine (IPA) salt (PC Code 128944), diglycolamine (DGA) salt (PC Code 128931), and potassium (K) salt (PC Code 129043). According to the Status of Pesticides in Registration, Reregistration, and Special Review (Rainbow Report; 1998), the following salts of dicamba have been cancelled: the diethanolamine salt (PC Code 029803), monoethanolamine dicamba (PC Code 029804), and aluminum salt of dicamba (PC Code 129042).

A 4/20/05 product registration query of the USEPA/OPP Chemical Ingredients (OPPIN) database identified several active end-use products (EPs) containing dicamba acid and/or salts as the active ingredient. These EPs, as well as all active Special Local Need (SLN) registrations, are listed below in Table 3.

Table 3. Dicamba End-use Products (EPs) Food/feed Uses.			
EPA Reg. No.	Status	% AI	Product Name
Dicamba acid (PC Code 029801)			
000228-00309	Conditionally Registered (10-Oct-1995)	10	RIVERDALE VETERAN 10G
000524-00507	Conditionally Registered (04-Jun-1999)	4.1	FALLOW MASTER BROAD SPECTRUM HERBICIDE
007969-00142	Conditionally Registered (04-Oct-1995)	69.4	SAN 821 H 600 HERBICIDE
007969-00148	Conditionally Registered (03-Dec-1996)	10.67	OPTILL HERBICIDE
071369-00030	Conditionally Registered (26-Sep-2001)	4.1	NUFARM GLYKAMBA BROAD SPECTRUM HERBICIDE
Dimethylamine (DMA) salt of dicamba (PC Code 029802) [1]			
000228-00295	Conditionally Registered (22-Aug-1994)	12.82	RIVERDALE VETERAN 720 HERBICIDE
000228-00296	Not listed in OPPIN Summary Report		
000352-00614	Conditionally Registered (30-Jan-2002)	12.4	DUPONT CIMARRON MAX PART B
000352-00615	Conditionally Registered (30-Jan-2002)	12.25	DUPONT CIMARRON MAX HERBICIDE
002217-00639	Conditionally Registered (26-Sep-1980)	4.24	TRIMEC 875 HERBICIDE

Table 3. Dicamba End-use Products (EPs) Food/feed Uses.			
EPA Reg. No.	Status	% AI	Product Name
007969-00131	Conditionally Registered (30-Aug-1962)	48.2	BANVEL HERBICIDE
007969-00133	Conditionally Registered (01-Apr-1974)	12.4	WEEDMASTER HERBICIDE
051036-00289	Conditionally Registered (14-May-1997)	48.2	DICAMBA DMA 4# AG
051036-00308	Conditionally Registered (19-Oct-1998)	12.4	BANVEL + 2,4-D
Sodium (Na) salt of dicamba (PC Code 029806)			
000100-00923	Conditionally Registered (25-Sep-1998)	43.9	NORTHSTAR HERBICIDE
000100-00927	Conditionally Registered (14-Dec-1998)	55	RAVE HERBICIDE
000241-00359	Conditionally Registered (07-Feb-1995)	61.9	RESOLVE SG HERBICIDE
000241-00384	Conditionally Registered (17-Mar-1998)	58.9	AC 513,995 DG HERBICIDE
007969-00135	Conditionally Registered (25-Apr-1986)	23.15	BANVEL SGF HERBICIDE
007969-00140	Conditionally Registered (30-Jun-1994)	77	SAN845H HERBICIDE
007969-00150	Conditionally Registered (28-Jan-1999)	55	DISTINCT HERBICIDE
007969-00166	Conditionally Registered (26-Feb-1998)	69.3	CELEBRITY HERBICIDE
007969-00175	Conditionally Registered (04-Aug-1999)	46.6	CELEBRITY PLUS HERBICIDE
033906-00011	Conditionally Registered (04-Feb-2002)	55	NC-398 WG
042750-00043	Conditionally Registered (07-Oct-1998)	23.15	ALBAUGH DICAMBA SODIUM SALT
051036-00290	Conditionally Registered (01-Aug-1997)	23.15	DICAMBA DMA 2# AG
Isopropylamine (IPA) salt of dicamba (PC Code 128944)			
000524-00390	Conditionally Reregistered (22-May-1997)	7	FALLOW MASTER HERBICIDE
007969-00138	Conditionally Registered (07-Jan-1988)	40.32	IPA SALT OF DICAMBA
042750-00063	Conditionally Registered (31-May-2001)	7	FALLOW STAR
Diglycolamine (DGA) salt of dicamba (PC Code 128931)			
000100-00975	Conditionally Registered (25-Jan-2001)	28.4	TD HERBICIDE

Table 3. Dicamba End-use Products (EPs) Food/feed Uses.			
EPA Reg. No.	Status	% AI	Product Name
007969-00137	Conditionally Registered (23-Sep-1987)	56.8	CLARITY HERBICIDE
Potassium (K) salt of dicamba (PC Code 129043)			
007969-00136	Conditionally Registered (25-Apr-1986)	13.42	MARKSMAN HERBICIDE
033658-00016	Conditionally Registered (16-Aug-2000)	13.45	STRATOS DICAMBA+ATRAZINE AGRICULTURAL HERBICIDE
042750-00041	Conditionally Registered (22-May-1998)	13.42	DICAMBAZINE
051036-00307	Conditionally Registered (13-Oct-1998)	13.42	BANVEL + ATRAZINE

[1] Includes SLNs CO90000200, CO99001200, CO99001300, and CO99001400.

Use Pattern Profile: The Agency's Special Review and Reregistration Division (SRRD) issued a Use Closure Memorandum for Dicamba (Case No. 0065) on 8/2/05 in an attempt to provide use information that will be incorporated into the preliminary risk assessment for dicamba. The Dicamba Use Closure Memo resulted from the 11/4/04 SMART meeting and subsequent discussions and review of product labels with the following registrants: Albaugh, Inc., BASF Corporation, Gharda USA, Inc., and Syngenta Crop Protection, Inc. The Closure Memo serves as the Agency's record of common understanding on the uses of dicamba that will be supported and used in risk assessments, including currently registered product information. The registrants intend to support all currently registered uses described in the Use Closure Memorandum for Dicamba and all currently registered products.

The Dicamba Use Closure Memos's list of food/feed uses is reproduced in Table 4 with minor alteration to include information pertaining to preharvest intervals (PHI). The PHI information, added in the last column of Table 4, was obtained from the 2002 Food/Feed Use Patterns Summary for dicamba acid and salts prepared by a contractor for BEAD; the BEAD Use Patterns Tables are presented in Appendix 1.

Table 4. Dicamba Food/Feed Use Profile.				
Use Sites	Forms [1]	Max App. Rate (lb ae/A)	Max App. Rate (lb ae/A/year)	PHI/PGI/PFI/PSI [2]
Agricultural Crops/Soils	DMA Salt, Na Salt	2.0	2.0	
Agricultural Fallow/Idleland	All	2.0	2.0	Na salt: 37-day PHI (dry hay and grain) and 30-day PSI; IPA salt: 56-day PFI/PGI
Agricultural/Farm Premises	DMA Salt, DGA Salt	1.0	1.0	
Agricultural/Farm Structures/Buildings and Equipment	DMA Salt	1.0	1.0	
Asparagus	DMA Salt, Na Salt, DGA Salt	0.5	0.5	DMA salt, Na salt, and DGA salt: 1-day PHI
Barley [3]	DMA Salt, Na Salt, DGA Salt, IPA Salt	0.25	0.38	Dicamba acid: 15-day PHI; DMA salt: 30-day PSI, 37-day PHI (dry hay), and 7-day PGI (dairy animals); Na salt: 37-day PHI (dry hay and grain) and 30-day PSI; DGA salt: 7-day PHI; IPA salt: 56-day PFI/PGI
Corn (field, pop. seed, silage)	DMA Salt, Na Salt, DGA salt, K Salt	0.5	0.75	Corn unspecified - Dicamba acid: 40-day PFI/PGI and Na salt: 30- to 32-day PHI and 30-day PGI; Corn - DMA salt: 30-day PSI, 37-day PHI (dry hay), and 7-day PGI (dairy animals); Field corn - Dicamba acid: 40-day PFI/PGI and Na salt: 30- to 32-day PHI, 45-day PHI (fodder), 60-day PHI (grain), and 30-day PFI/PGI Pop corn - Dicamba acid: 40-day PFI/PGI and Na salt: 45-day PHI (fodder), 60-day PHI (grain), and 30-day PFI/PGI
Cotton	Dimethylamine Salt, DGA	0.25	2.0	
Hay	DMA Salt, Na Salt, DGA Salt	2.0 [4]	2.0	DMA salt: 30-day PSI, 7- to 37-day PHI (dry hay), and 7-day PGI (dairy animals)
Millet (Proso) [3]	DMA Salt	0.125	0.125	

Table 4. Dicamba Food/Feed Use Profile.				
Use Sites	Forms [1]	Max App. Rate (lb ae/A)	Max App. Rate (lb ae/A/year)	PHI/PGI/PFI/PSI [2]
Oats	DMA Salt, Na Salt, DGA Salt	0.125	1.0	Dicamba acid: 15-day PHI; DMA salt: 30-day PSI, 37-day PHI (dry hay), and 7-day PGI (dairy animals); Na salt: 37-day PHI (dry hay); IPA salt: 56-day PFI/PGI
Pastures [5]	DMA Salt, Na Salt, DGA Salt	2.0	2.0	DMA salt: 30-day PSI, 37-day PHI (dry hay), 7- to 70-day PHI (dry hay), 7-day PGI (dairy animals), and 40-day PGI Na salt: 30-day PSI and 37-day PHI (dry hay and grain); DGA salt: 30-day PSI and 7-day PGI (dairy animals)
		7.7	7.7	
Rangeland [5]	DMA Salt, Na Salt, DGA Salt	2.0	2.0	DMA salt: 30-day PSI, 37-day PHI (dry hay), 7- to 70-day PHI (dry hay), 7-day PGI (dairy animals), and 40-day PGI; Na salt: 30-day PSI and 37-day PHI (dry hay and grain); DGA salt: 30-day PSI and 7-day PGI (dairy animals)
		7.7	7.7	
Rye	DMA Salt	0.5	1.0	DMA salt: 30-day PSI, 37-day PHI (dry hay), and 7-day PGI (dairy animals)
Sorghum	All	0.2748	0.5	Dicamba acid: 15-day PHI and 40-day PFI/PGI; DMA salt: 30-day PSI, 37-day PHI (dry hay), and 7-day PGI (dairy animals) Na salt: 30-day PGI and PHI; IPA salt: 56-day PFI/PGI; K salt: 21-day PFI/PGI and 30- to 37-day PHI
Soybean	Sodium Salt, DGA	2.0	2.0	
Sudangrass	DMA Salt	0.5 (as listed for hay)	1.0	DMA salt: 30-day PSI, 37-day PHI (dry hay), and 7-day PGI (dairy animals)
Sugarcane	DMA Salt, Na Salt, DGA salt	2.8	2.8	DMA salt: 30-day PSI, 37-day PHI (dry hay), and 7-day PGI (dairy animals)

Table 4. Dicamba Food/Feed Use Profile.				
Use Sites	Forms [1]	Max App. Rate (lb ae/A)	Max App. Rate (lb ae/A/year)	PHI/PGI/PFI/PSI [2]
Wheat [3]	DMA Salt, Na Salt, DGA Salt, IPA Salt	0.5	1.0	Dicamba acid: 15-day PHI; DMA salt: 30-day PSI, 37-day PHI (dry hay), 7- to 14-day PHI, and 7-day PGI (dairy animals) Na salt: 30-day PSI and 37-day PHI (dry hay and grain) IPA salt: 56-day PFI/PGI

[1] There are five forms of dicamba used in this Master Label: Dimethylamine [DMA] Salt (PC Code 029802), Sodium [Na] Salt (PC Code 029806), Diglycolamine [DGA] (PC Code 128931), Isopropylamine Salt [IPA] (PC Code 128944), and Potassium [K] Salt (PC Code 129043).

[2] PHI = Preharvest interval; PGI = Pregrazing interval; PFI = Prefeeding interval; PSI = Preslaughter interval. This information was obtained from the summaries of the food/feed use patterns of dicamba as prepared by BEAD (see Appendix 1).

[3] SLN registration CO990001300 is for small grains at 1.0 lbs ae/A. Based on Agency data, barley, millet, and wheat are listed as small grains.

[4] Based on label (EPA Reg. Nos. 51036-289 and 7969-131).

[5] Label (EPA Reg. No. 100-884) lists 7.7 lb ae/A as the maximum rate for spot treatment for pasture and rangeland uses. The 2.0 lbs ae/A is what the registrant stated at the SMART meeting as the rate they intended to support.

Conclusions: The available residue chemistry data for dicamba acids and/or salts were re-evaluated in this Residue Chemistry Chapter for adequacy in fulfilling the maximum use patterns listed for each crop in the 8/2/05 Dicamba Use Closure Memorandum. For sugarcane, the maximum seasonal rates listed in the Dicamba Use Closure Memo are not supported by adequate field trial data. To satisfy reregistration requirements, this Chapter is requiring the registrants to submit additional data. Alternatively, the registrants are given the option of revising product labels for consistency with the reviewed data. In addition, label revisions are required to specify the appropriate rotational crop restrictions based on the submitted confined rotational crop study.

HED notes that labels of basic producers have been revised to specify that aerial applications should be made in spray volumes of >2 gallons/A precluding the need for residue data reflecting ultra low volume application (ULV). HED requests RD to verify that the labels of non-basic producers are also amended to specify this exact information. Finally, HED wishes to comment on certain food/feed sites listed in the 8/2/05 Dicamba Use Closure Memorandum. The sites 'Agricultural Crops/Soils' and 'Agricultural Fallow/Idleland' are very broad uses and should be deleted unless the registrants submit residue data on representative commodities of all crop groups. The sites 'Agricultural/Farm Premises' and 'Agricultural/Farm Structures/Buildings and Equipment' are classified as nonfood uses since dicamba application on these sites would not be expected to result in significant dicamba residues that could eventually be consumed.

A tabular summary of the residue chemistry science assessments for the reregistration of dicamba is presented in Table 5. The conclusions listed in Table 5 regarding the reregistration eligibility of the food/feed uses of dicamba are based on the food/feed uses summarized in Table 4. When end-use product DCIs are developed, RD should require that all end-use product labels (e.g., MAI labels, SLNs, and products subject to the generic data exemption) be amended such that they are consistent with the master label.

Table 5. Residue Chemistry Science Assessment for the Reregistration of Dicamba.			
GLN Data Requirements	**Tolerances (ppm) [40 CFR §180.227]**	**Additional Data Needed?**	**MRID Nos.**[1]
860.1200: Directions for Use	N/A = Not Applicable	Yes[2]	See Appendix 1
860.1300: Nature of the Residue - Plants	N/A	No	00022745 00022753 00025344 00036921 00079708 00079747 00102945 00118473 40642801[3]
860.1300: Nature of the Residue - Animals	N/A	No	00077779 00145248 43245201[4] 43245202[4] 43461701[5] 43554205[5]
860.1340: Residue Analytical Method			
- Plant Commodities	N/A	Yes [6]	00028263 00079736 00088173 00162206 40233501 42883201[7] 43814002[7] 43814103[8] 43814104[8]
- Animal Commodities	N/A	Yes [9]	00079744
860.1360: Multiresidue Method	N/A	Yes [10]	PAM Vol. I
860.1380: Storage Stability Data			
- Plant Commodities	N/A	Yes[11]	40547911[3] 40663801 43245204[12] 43245205[12] 43245206[12] 43274501[12] 43370701[13] 43814102[8] 43866601[14]
- Animal Commodities	N/A	No	46668101[15]
860.1400: Magnitude of the Residue - Water, Fish, and Irrigated Crops	N/A	No	
860.1460: Magnitude of the Residue - Food Handling	N/A	No	
860.1480: Magnitude of the Residue - Meat, Milk, Poultry, Eggs			
- Milk and the Fat, Meat, and Meat Byproducts of Cattle, Goats, Hogs, Horses, and Sheep	0.2 for fat, meat, and meat byproducts; 0.3 for milk; 1.5 for kidney and liver	No	00079742 00116671 44891303[16]
- Eggs and the Fat, Meat, and Meat Byproducts of Poultry	None established	No	00148127

Table 5. Residue Chemistry Science Assessment for the Reregistration of Dicamba.			
GLN Data Requirements	**Tolerances (ppm) [40 CFR §180.227]**	**Additional Data Needed?**	**MRID Nos.**[1]
860.1500: Crop Field Trials			
Legume Vegetables (Crop Group 6)			
- Soybean seed	10.0	No[17]	00102944 43814101[8] 44089307[14]
Foliage of Legume Vegetables (Crop Group 7)			
- Soybean forage and hay	None established	No[18]	00075729 00102944 43814101[8] 44089307[14]
Cereal Grains (Crop Group 15)			
- Barley grain	6.0	No	00028252 00162206 44089304[14]
- Corn, field, grain	0.5	No	00015636 00015637 00015640 00015641 00015642 00015786 00016435 00016436 00016437 00016438 00022612 00022613 00022618 00023584 00023684 00025364 00025383 00028269 00075715 00088172 44089303[14]
- Corn, pop, grain	0.5	No[19]	
- Millet grain	0.5	No[20]	00025330
- Oat grain	0.5	No[20]	00023687 00028252
- Rye grain	None established	No[20]	
- Sorghum grain	3.0	No[20]	00022622 00078448 43245203[12] 44089306[21]
- Wheat grain	2.0	Yes[22]	00004541 00004566 00023687 00025394 00028398 00162206 40663801 44089305[14]
Forage, Fodder, and Straw of Cereal Grains (Crop Group 16)			
- Barley hay and straw	2.0 for hay; 15.0 for straw	No	00028252 00162206 44089304[14]

Table 5. Residue Chemistry Science Assessment for the Reregistration of Dicamba.			
GLN Data Requirements	**Tolerances (ppm) [40 CFR §180.227]**	**Additional Data Needed?**	**MRID Nos.**[1]
- Corn, field, forage and stover	0.5 for corn forage and stover; 3.0 for field corn forage and stover	Yes[23]	00015636 00015637 00015640 00015641 00015642 00015786 00016435 00016436 00016437 00016438 00022612 00022613 00022618 00023584 00023684 00025364 00025383 00028269 00075715 00088172 44089303[14]
- Corn, pop, stover	3.0	No[23]	
- Millet forage, hay, and straw	0.5 for straw	No[23]	00025330
- Oat forage, hay, and straw	80 for forage; 20 for hay; 0.5 for straw	No[23]	00023687 00028252
- Rye forage and straw	None established	No[23]	
- Sorghum forage and stover	3.0 for forage and stover	No[24]	00022622 00078448 43245203[12] 44089306[2525]
- Wheat forage, hay, and straw	80.0 for forage; 20.0 for hay; 30.0 for straw	Yes[26]	00004541 00004566 00023687 00025394 00055662 00162206 43274501[27] 44089305[14] 44891302[28]
Grass, Forage, Fodder, and Hay (Crop Group 17) - Pasture and rangeland grasses	125 for forage; 200 for hay	No[29]	00028173 00028200 00028267 00028268 43370701[30]
Miscellaneous Commodities			
- Asparagus	4.0	No[31]	00025338 43245206[12] 43425803[12]
- Aspirated grain fractions	5100	Yes[32]	43245205[12] 43814102[8] 44089305[14]
- Cotton, undelinted seed, and gin byproducts	5.0 for cottonseed	Yes[33]	43814001[31] 45196801[27]
- Sugarcane	0.1 for cane, fodder, and forage	Yes[34]	00030701 00079738 00149626 44089302[25]
860.1520: Processed Food/Feed			
- Barley grain	None established	No[23]	
- Corn grain	None established	No	41187301[27]
- Cotton	5.0 for meal	No	66378
- Millet grain	None established	No[35]	

Table 5. Residue Chemistry Science Assessment for the Reregistration of Dicamba.			
GLN Data Requirements	Tolerances (ppm) [40 CFR §180.227]	Additional Data Needed?	MRID Nos.[1]
- Oat	None established	No[23]	
- Sorghum	None established	No[36]	
- Soybean	13.0 for hulls	No	43814102[8]
- Sugarcane	2.0 for molasses	No[37]	43245204[12]
- Wheat	None established	No	40663801[38] 42675901[39]
860.1650: Submittal of Analytical Standards	N/A	Yes[40]	
860.1850: Confined Accumulation in Rotational Crops	Not applicable	No	41972001[41] 43698601[42]
860.1900: Field Accumulation in Rotational Crops	None established	No[43]	

1. Unless otherwise specified by an endnote, all references were originally reviewed in the 8/12/83 Residue Chemistry Chapter of the Dicamba Registration Standard and re-summarized in the 6/30/89 Residue Chemistry Chapter of the Dicamba (SRR) Registration Standard.

2. For sugarcane, the maximum seasonal rates listed in the 8/2/05 Dicamba Use Closure Memorandum are not supported by adequate field trial data. To satisfy reregistration requirements, this Chapter is requiring the registrants to submit additional data. Alternatively, the registrants are given the option of revising product labels for consistency with the reviewed data. In addition, label revisions are required to specify the appropriate rotational crop restrictions based on the submitted confined rotational crop study.

   HED requests RD to verify that the labels of non-basic producers are amended to specify that aerial applications should be made in spray volumes of >2 gallons/A; this would preclude the need for residue data reflecting ultra low volume application (ULV).

   HED wishes to comment on certain food/feed sites listed in the 8/2/05 Dicamba Use Closure Memorandum. The sites 'Agricultural Crops/Soils' and 'Agricultural Fallow/Idleland' are very broad uses and should be deleted unless the registrants submit residue data on representative commodities of all crop groups. The sites 'Agricultural/Farm Premises' and 'Agricultural/Farm Structures/Buildings and Equipment' are classified as nonfood uses since dicamba application on these sites would not be expected to result in significant dicamba residues that could eventually be consumed.

3. DEB Nos. 4424 and 4425, 5/18/89, E. Haeberer.

4. DP Barcode D204482, 3/7/96, L. Cheng.

5. DP Barcode D226526, 6/24/96, D. Miller. [This memo acknowledges receipt of the cited studies relevant to confirmation of residues using the enforcement analytical method. This HED memo stated that the study is presently in-house awaiting review.]

6. In conjunction with PP#4F3041, additional method validation data using Method AM-0691B-0297-4 are required for barley grain and straw at fortification levels of 6 and 15 ppm, respectively, and for wheat straw at 30 ppm because the maximum residues obtained from the respective field trials were not validated at these levels. In addition, the registrants are required to submit additional method validation data using Method AM-0941-1094-0 for soybean seeds at a spike level of 10 ppm. The registrants have committed to generate these data.

7. DP Barcodes D220469, D220471, D220473, and D220430, 5/2/96, F. Griffith;
   DP Barcode D227359, 6/27/96, F. Griffith; and
   DP Barcode D194776, 12/14/93, D. Miller.

8. DP Barcodes D223283, D223292, D223300, D223311, D223316, D223320, D223355, D223356, D223361, D223363, D223373, D223374, D223380, and D223383, 7/29/96, S. Knizner, W. Dykstra, and C. Lewis.

9. The Pesticide Analytical Manual (PAM) Vol. II lists Method II, a GC/ECD method which is identical to Method I, for the enforcement of dicamba animal tolerances. Based on the results of animal metabolism study, which showed that acid hydrolysis can additionally extract up to 30% of TRR in goat liver, HED is requiring the registrants to revise/improve Method II to include an acid hydrolysis step and submit additional validation data for animal matrices using the improved method. Method II should also be re-written specifically for the analysis of the parent dicamba and its metabolite 3,6-dichloro-2-hydroxybenzoic acid metabolite in animal matrices.

10. There are no multiresidue methods recovery data for the dicamba metabolites of concern (5-OH dicamba and DCSA), and these data are required. The registrants are required to follow the directions for the protocols found in PAM Vol. I, Appendix II under paragraph (d)(1) of OPPTS 860.1360 GLN, starting with the decision tree for multiresidue methods testing and the accompanying guidance found in the suggestions for producing quality data.

11. Storage stability data are required for sugarcane molasses to validate the interval and conditions (64 days, <-1 °C) of samples collected and analyzed from the submitted sugarcane processing study (MRID 43245204).

12. DP Barcodes D204488, D204809, and D209229, 7/14/97, L. Cheng.

13. DP Barcode D207649, 3/11/96, L. Cheng.

14. DP Barcode D228703, 7/16/98, S. Chun.

15. [redacted]

16. [redacted]

17. For consistency with the reviewed data, HED will have no objection if the registrants revise their labels to specify a maximum seasonal rate of 2.5 lb ae/A on soybeans since this rate is supported by adequate data. The available data indicate that the established tolerance of 10 ppm for soybean seed will not be exceeded when representative salt formulations of dicamba are applied at a slightly exaggerated total rate of 2.5 lb ae/A.

18. It is the current Agency policy to allow label restrictions on the feeding/grazing of livestock animals on soybean forage and hay, thus, precluding the need for residue data and tolerances for these soybean commodities. HED defers to RD for verifying whether such restrictions exist on product labels. If such restrictions appear on the labels, then residue data and tolerances for soybean forage and hay are not necessary. If no such restrictions appear on the labels, then the registrants are required to propose tolerances for soybean forage and hay at 0.1 ppm each. Concomitant with these tolerance proposals, the registrants are required to propose a maximum seasonal rate of 0.5 lb ae/A for preplant application on soybean grown for forage and hay only.

19. HED will allow the translation of available/requested field trial data from some crop commodities to agronomically related commodities with similar uses. The available/requested data for field corn grain and stover may be translated to pop corn grain and stover. The available/requested data for wheat grain, forage, hay, and straw may be translated to the respective commodities of proso millet, oat, and rye. Finally, the available wheat grain processing data may be translated to barley and oats. Where translation of data is allowed, any HED recommendations with regards to label revisions as well as tolerance reassessment should apply to all respective crop commodities.

20. HED is recommending label revision to specify a 30-day PHI for sorghum grain for consistency with the reviewed data.

21. DP Barcodes D304019, D306687-D306690, x/x/05, C. Olinger.

22. The registrants are required to submit a complete set of residue data on wheat grain reflecting a maximum seasonal rate of 1.0 lb ae/A. Alternatively, the registrants may rely on the available data provided they are willing to revise product labels for consistency with the reviewed data. If the registrants elect to choose the latter option, then they will be required to revise product labels to specify a maximum seasonal rate of 0.5 lb ae/A. The existing tolerance of 2.0 ppm for wheat grain will be considered adequate *if* the registrants elect to revise product labels.

23. The registrants are required to submit additional data on field corn forage and stover reflecting a maximum seasonal rate of 0.75 lb ae/A. Alternatively, the registrants may rely on the available data provided they are willing to revise product labels for consistency with the reviewed data. If the registrants elect to choose the latter option, then they will be required to revise product labels to specify a maximum seasonal rate of 2.75 lb ae/A, a 39-day PHI/PGI for forage, and a 66-day PHI for stover. The existing tolerances of 3.0 ppm for field corn forage and fodder would remain adequate if the registrants elect to revise product labels.

24. For consistency with the reviewed data, label revisions are required to specify: (i) a 20-day PHI and a maximum single/seasonal rate of 0.25 lb ae/A for sorghum forage; and (ii) a 30-day PHI for sorghum fodder (stover) at a maximum seasonal rate of 0.5 lb ae/A. Following an examination of use directions for sorghum, HED will allow a lower use rate for forage since this RAC will be harvested prior to the second crop application.

25. D304019, D306687-D306690, 12/05, C. Olinger.

26. The registrants are required to submit additional data on wheat straw reflecting a maximum seasonal rate of 1.0 lb ae/A. Alternatively, the registrants may rely on the available data provided they are willing to revise product labels for consistency with the reviewed data. If the registrants elect to choose the latter option, then they will be required to revise product labels to specify a maximum seasonal rate of 0.5 lb ae/A and a 7-day PHI for wheat straw. The existing tolerance of 30 ppm for wheat straw will be considered adequate *if* the registrants elect to revise product labels.

27. DP Barcodes D220430, D220469, D220471, and D220473, 5/2/96, F. Griffith.

28. D220469, D220471, D220473, and D220430, 11/24/05, C. Olinger.

29. HED is requesting RD to verify that all dicamba labels specify a 0-day PHI/PGI for grass forage and a 7-day PHI for grass hay when applied at a maximum of 2.0 lb ae/A. In addition, HED is recommending the removal of the spot treatment use on pastures and rangeland at 7.7 lb ae/A (from EPA Reg. No. 100-884) because there are no available data supporting this use rate; alternatively, the registrants may submit data to support this application rate.

30. This grass forage and hay submission was initially reviewed in a 3/11/96 memo (DP Barcode 207649, L Cheng) to fulfill reregistration requirements. The study was re-evaluated in conjunction with PP#6F4604: (i) DP Barcodes D220469, D220471, D220473, and D220430, 5/2/96, F. Griffith; and (ii) DP Barcodes D228694 and D239967, 6/25/98, S. Chun.

31. There are adequate residue data on asparagus. However, HED requests RD to verify that the label PHI for asparagus is 24 hours or 1 day for consistency with the reviewed data.

32. Data on the aspirated grain fractions of field corn are required since an examination of the BEAD Use Pattern Table indicates that various salt formulations of dicamba may be applied early and late postemergence to the crop. The required data on the aspirated grain fractions of corn should analyze for all residues of concern (parent, 5-OH dicamba, and DCSA).

33. Additional information is required before the cotton gin by-product field trials can be considered acceptable. (D220469, D220471, D220473, and D220430, 11/24/05, C. Olinger).

34. The registrants are required to submit additional data on sugarcane reflecting a maximum single/yearly rate of 2.8 lb ae/A. Alternatively, the registrants may rely on the available data provided they are willing to revise product labels for consistency with the reviewed data. If the registrants elect to choose the latter option, then they will be required to revise product labels to specify a maximum seasonal rate of 2.0 lb ae/A and an 87-day PHI for sugarcane. The existing tolerance of 0.1 ppm for sugarcane is inadequate and HED is recommending that it be reassessed at 0.3 ppm *if* the registrants elect to revise product labels as detailed

above

35. According to Table 1 of OPPTS 860.1000, the only processed commodity associated with millet is flour. Endnote 44 of Table 1 specify that millet flour is not produced significantly in the U.S. for human consumption, and residue data are not needed at this time.

36. The Dicamba SRR (6/89) required a sorghum processing study depicting the combined residues of dicamba and its hydroxy metabolite in milled products (flour and starch) from sorghum grain bearing measurable, weathered residues. In response, the registrant submitted a protocol (S. Knizner, 6/11/93) and a rebuttal to the review of the protocol (R. Perfetti, 10/20/93). The Agency concluded that residue data are not required for sorghum flour or starch. Based on this previous HED determination, a sorghum processing study is not required for reregistration.

37. Pending submission of supporting storage stability data for sugarcane molasses, an adequate sugarcane processing study is available.

38. DEB Nos. 3968, 3969, 4018, and 4019, 11/4/88, F. Griffith.

39. DP Barcodes D189039, D189041, and D189043, 4/23/93, L. Cheng.

40. Analytical standards for dicamba acid, DMA salt of dicamba, and Na salt of dicamba are currently available (as of 5/6/2005) in the National Pesticide Standards Repository; however, no standards are available for 5-OH dicamba and DCSA. Analytical reference standards of dicamba and its regulated metabolites must be supplied, and supplies replenished as requested by the Repository. The reference standards should be sent to the Analytical Chemistry Lab, which is located at Fort Meade, to the attention of either Theresa Cole or Frederic Siegelman at the following address:

    USEPA
    National Pesticide Standards Repository/Analytical Chemistry Branch/OPP
    701 Mapes Road
    Fort George G. Meade, MD 20755-5350
    (Note that the mail will be returned if the extended zip code is not used.)

41. DP Barcode D197629, 2/16/96, L. Cheng.

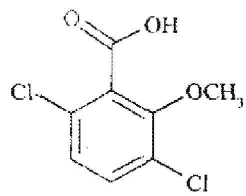
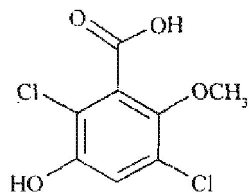
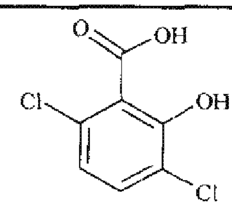
42. DP Barcodes D228694 and D239967, 6/25/98, S. Chun.

43. Limited and/or extensive field accumulation studies with dicamba need not be conducted and rotational crop tolerances need not be established *provided* the registrants are willing to amend all dicamba labels with food/feed use claims to specify a 120-day plantback interval when dicamba is applied at a maximum seasonal rate of 0.75 lb ae/A or less. At application rates of 0.75-2.0 lb ae/A, the labels should specify that only the crops with established dicamba tolerances can be rotated.

SUMMARY OF SCIENCE FINDINGS

860.1300 Nature of the Residue - Plants

The nature of the residue in plants is adequately understood. The residues of concern in barley, corn, cotton, grasses, oat, proso millet, sorghum, sugarcane, and wheat are dicamba and its 3,6-dichloro-5-hydroxybenzoic acid (5-OH dicamba) metabolite; these are the residues currently regulated in 40 CFR §180.227 (a)(1). In asparagus, the residues of concern are dicamba and its 3,6-dichloro-2-hydroxybenzoic acid metabolite [40 CFR §180.227 (a)(2)]; the metabolite 3,6-dichloro-2-hydroxybenzoic acid metabolite is also referred to as 3,6-dichlorosalicylic acid (DCSA). The residues of concern in/on aspirated grain fractions and soybeans are dicamba, 5-OH dicamba, and DCSA [40 CFR §180.227 (a)(3)]. The current tolerance definitions are appropriate for all crop commodities with registered uses. The chemical names and structures of dicamba and its regulated metabolites are depicted below in Figure 1.

Figure 1. Chemical names and structures of dicamba and its metabolites.		
		
Dicamba (3,6-dichloro-*o*-anisic acid)	**5-hydroxy dicamba** (3,6-dichloro-5-hydroxy-*o*-anisic acid)	**DCSA** (3,6-dichloro-2-hydroxybenzoic acid or 3,6-dichlorosalicylic acid)

The available plant metabolism studies with dicamba were originally reviewed in the 8/12/83 Residue Chemistry Chapter of the Dicamba Registration Standard and re-summarized in the 6/30/89 Residue Chemistry Chapter of the Dicamba (SRR) Registration Standard. The Dicamba SRR concluded that dicamba is rapidly absorbed and translocated by grasses (MRID 00022753), grapes (MRID 00022745), black valentine beans (MRID 00079708), wheat and bluegrass (MRID 00036921), and soybeans (MRID 00102945). Dicamba is also rapidly absorbed by sugarcane following foliar application but it is very slowly translocated from the leaves to the roots (MRID 00079747). Dicamba is metabolized in plants mainly by demethylation and hydroxylation.

860.1300 Nature of the Residue - Livestock

MRID 43245201 (Ruminant) (DP Barcode D204482. 3/7/96, L. Cheng)
MRID 43245202 (Poultry) (DP Barcode D204482. 3/7/96, L. Cheng)

The nature of the residue in animals is adequately understood based on acceptable metabolism studies conducted on ruminants and poultry. The compounds identified in these studies include dicamba, 3,6-dichlorosalicylic acid (DCSA) and 2-amino-3,6-dichlorophenol. The latter compound was identified only in hen liver at <1% and thus, need not be included in the tolerance expression. The residues of concern in meat, milk, poultry and eggs remain unchanged and consist of dicamba and 3,6-dichloro-2-hydroxybenzoic acid [40 CFR §180.227 (a)(2)]. The chemical structures of dicamba residues of concern in animals are depicted in Figure 1. The salient features of the reviewed animal metabolism studies are summarized below.

Ruminants: In a goat metabolism study (MRID 43245201), [^{14}C]dicamba was administered orally once daily for four consecutive days to two goats (Goat A and Goat B) at a dose equivalent to 5.91 or 630.8 ppm, respectively in the diet. The test substance had a radiochemical purity of 99% and a specific activity of 3.99 mCi/mmol. The dose rates were based on actual body weights of 41 and 39 kg for goats A and B, respectively, and a feed consumption of approximately 63-68 grams of feed/kg of body weight/day. Only analyses of tissue samples from Goat A were presented. The 5.91 ppm dose is substantially below the estimated maximum theoretical dietary exposure of 1153.63 ppm (see Table 6).

Milk was collected twice daily. Within 24 hours following the final dose, the test animals were sacrificed and kidney, liver, muscle, and fat were collected. Samples were stored frozen (-20 °C) until analysis. In a follow-up submission (No MRID No.; DP Barcode D226526, 6/24/96, D. Miller), the registrant stated that in no case were samples stored for longer than 6 months (from date of collection) prior to preliminary chromatographic analyses. The follow-up review concluded that there are no storage stability concerns associated with the previously submitted metabolism studies.

The total radioactive residues (TRR, expressed as dicamba equivalents) in samples taken from the treated goat were: 0.0007-0.0020 ppm in milk, 0.0105 ppm in fat, 0.0536 ppm in kidney, 0.0141 ppm in liver, and 0.0040 ppm in muscle. Kidney, liver, and fat samples were subjected to residue extraction procedures using organic solvents, and the nonextractable residues were acid hydrolyzed to release bound residues. The extractable residues were analyzed by TLC and HPLC, and the identity of dicamba was confirmed by GC/MS.

Approximately 95-100% of the TRRs were extractable from kidney, liver, and fat and 64-100% of the TRRs were identified/characterized in the three matrices. Dicamba *per se*, accounting for 63.28-92.82% of the TRR, was detected in kidney, liver, and fat. The metabolite DCSA was a major metabolite in kidney (10.55% TRR; 0.0057 ppm) and liver (11.77% TRR; 0.0017 ppm) and only a minor component in fat (1.23% TRR; 0.0001 ppm). An unknown, accounting for <10% of the TRR was detected in liver. A trace (0.006% TRR) of 5-OH dicamba (a plant dicamba metabolite) was detected in urine. Dicamba metabolism in ruminants is proposed by the registrant to proceed via formation of DCSA or 5-OH dicamba.

In its review, HED noted that the ^{14}C-residues in goat milk and muscle were not characterized/identified, and the animals were dosed at only about 6 ppm. The registrant stated that ^{14}C-residues from milk and muscle were not characterized because of low total radioactivity in the samples. HED concludes that in this case, characterization and identification of ^{14}C-residues in milk and muscle is not critical because residues would be expected to be qualitatively similar to those found in fat, kidney, and liver. In addition, HED notes that the registrants have committed to conducting a ruminant feeding study at a feeding level of 1,000 ppm. The residue to be regulated consists of dicamba and DCSA as currently stated in the tolerance expression.

The initial study review had required that samples from these animal metabolism studies must be analyzed using GLC/EC method AM-0685 to ensure that these compounds can be adequately recovered. Method AM-0685 has been successfully validated in milk, muscle, liver, kidney, and fat in an Agency laboratory (Dicamba SRR, 6/30/89). In a follow-up submission (No MRID No.; DP Barcode D226526, 6/24/96, D. Miller), the registrant has responded that study reports have now been submitted relating to new method validation (MRID 43461701) and confirmation of residues using the enforcement analytical method (MRID 43554205). The 6/24/96 memo stated that these studies are presently in-house awaiting review.

Poultry: In a poultry metabolism study (MRID 43245202), [^{14}C]dicamba was administered orally via capsule once daily for four consecutive days to five laying hens at a dose equivalent to 10 ppm in the diet. An additional three hens were orally dosed at 500 ppm. Only the analyses of the hens dosed at 10 ppm were presented. The 10 ppm dose is ~1.9x the estimated maximum theoretical dietary exposure of 5.2 ppm (see Table 6). The test substance had a radiochemical purity of 99% and a specific activity of 9.21 mCi/mmol. Two additional hens served as controls. Eggs were collected twice daily. Within 24 hours following the final dose, the test animals were sacrificed and liver, muscle, and fat samples were collected. Samples were stored frozen (-20°C) until analysis. All initial analyses were performed within 6 months of sample collection.

TRRs, expressed as dicamba equivalents, in samples taken from the treated hens were: 0.0014-0.004 ppm in egg yolk; 0.0018-0.0037 ppm in egg white; 0.0029 ppm in liver; 0.0003 ppm in breast muscle; 0.0005 ppm in leg muscle; and 0.0002 ppm in fat. The maximum residues were found in egg whites and egg yolks (0.004 ppm). Although TRRs were <0.01 ppm for all matrices, residue characterization was conducted on liver and eggs. Radioactive residues in these matrices were extracted using organic solvents, and the nonextractable residues were acid hydrolyzed to release bound residues. The extractable residues were analyzed by TLC, and the identity of metabolites was confirmed by HPLC.

The results show that virtually 100% of the TRRs from liver and egg were extractable, and 95-97% of the TRRs were identified/characterized in the two matrices. Dicamba *per se* accounted for 61.16% and 95.25% of the TRR in liver and eggs, respectively. The metabolite 2A36DCP was detected in liver (35.76% TRR;, 0.001 ppm) but not in eggs. The metabolites DCSA and 5-OH dicamba were not detected in liver or eggs but were detected in excreta and together accounted for <3% of the TRR. Dicamba metabolism in poultry is proposed by the registrant to proceed via formation of DCSA subsequently followed by formation of 2A36DCP.

860.1340 Residue Analytical Methods

Plant commodities

The Pesticide Analytical Manual (PAM) Vol. II lists Method I (AM 0268A), a GC method with electron capture detection (GC/ECD) for the enforcement of dicamba tolerances for plant commodities. Using this method, residues of dicamba and its metabolites are extracted from crop commodities with sulfuric acid-ether mixture, and the extract is passed through a buffered Celite column. Residues of dicamba and its 5-hydroxy metabolite are determined by GC/ECD by comparing the chromatograms with calibration curves made with methyl 2-methoxy-3, 6-dichlorobenzoate and methyl 2,5-dimethoxy-3, 6-dichlorobenzoate as standards. Residues of 3,5-dichloro-o-anisic acid are also determined by GC/ECD by comparing the chromatograms with a calibration curve made with methyl 2-methoxy-3, 5-dichlorobenzoate as the standard. Method I was validated by Agency chemists on corn and sorghum commodities as matrices. The sensitivity of the method is listed at 0.05 ppm.

An improved plant enforcement method (GC/ECD) has resulted from the requirements of the 6/30/89 Residue Chemistry Chapter of the Dicamba (SRR). The Chapter requested that Method AM-0691A or B, both of which were modifications to Method I of PAM Vol. II (AM 0268A), be subjected to an independent laboratory validation (ILV) because the method procedures included an acid hydrolysis step which increased the extraction efficiency of dicamba residues from various commodities. Method AM-0691B-0593-2 (MRID 42883201) underwent successful ILV (DP Barcode D194776, 12/14/93, D. Miller) and EPA method validation (DP Barcode D232478, 1/21/97, J Stokes). In principle, Method AM-0691B has not changed over years. In brief, samples are treated with 1 N HCl and hydrolyzed for 1.5 hours in a 95 °C water bath. The hydrolysate is adjusted to pH ≥8 with a 50 mL aliquot removed for analysis, then acidified to pH <1, and extracted twice with diethyl ether. The combined ether extracts are concentrated and then methylated with diazomethane. Cleanup is by silica gel columns. Determination of the methylated residues is by capillary ^{63}NiEC-GC. Some of the minor changes that occurred in this method pertain to the extraction step (no extraction with 80% ethanol in 1 N HCl), changes in the GC columns, and the addition of a GC-MSD confirmatory step. [Note: The use of diazomethane for enforcement methods is being discouraged by the Agency wherever an alternative is feasible. The registrant has shown elsewhere (DEB memo 3/27/90, F. Griffith; DEB No. 6712, 7/26/90, S. Funk) that neither N,O-bis(trimethylsilyl)-trifluoroacetamide (BSTFA) nor BF_3/CH_3OH will derivatize dicamba. Therefore, the continued use of diazomethane is necessitated.]

Pending a re-write of the method to incorporate suggested changes/corrections made by Agency chemists from ACL, the method will be forwarded to FDA for publication in PAM Vol. II as an addition to the entries of available enforcement methods for dicamba. It is noted that this method was recently superceded by method AM-0691B-0297-4 (MRID 44394102), which consists of a more detailed step-by-step description of the procedures, GC-MS confirmatory tests, and additional recovery data. The LOQ for dicamba and 5-OH dicamba is 0.02 ppm.

The data-collection method, used for the analysis of samples collected from field and processing studies intended to replace Craven data, was AM-0691B. In all cases, the concurrent method recoveries were well within the acceptable range of 70-120%. However, in conjunction with PP#4F3041 (DP Barcode D228703, 7/16/98, S. Chun), additional method validation data using Method AM-0691B-0297-4 were requested for barley grain and straw at fortification levels of 6 and 15 ppm. respectively, and for wheat straw at 30 ppm because the maximum residues obtained from the respective field trials were not validated at these fortification levels.

The data-collection method, used for the analysis of samples, collected from soybean field and processing studies, was the capillary GC-EC residue analytical Method AM-0941-1094-0. The extraction steps of Method AM-0941-1094-0 and Method AM-0691B-0297-4 are essentially identical. HED's PIRAT has previously determined that adequate validation data for Method AM-0941-1094-0 are available and, therefore, will not require additional ILV or PMV for this method. The registrant has committed to performing additional residue validation for soybean seeds at a fortification level of 10 ppm using method AM-0941-1094-0 in order validate the results of the soybean field trials.

Animal commodities

The Pesticide Analytical Manual (PAM) Vol. II lists Method II, a GC/ECD method which is identical to Method I, for the enforcement of dicamba animal tolerances. The sensitivity of the method is listed at 0.01 ppm. Based on the results of animal metabolism study, which showed that acid hydrolysis can additionally extract up to 30% of TRR in goat liver, HED is requiring the registrants to revise/improve Method II to include an acid hydrolysis step and submit additional validation data for animal matrices using the improved method. Method II should also be re-written specifically for the analysis of the parent dicamba and its metabolite 3,6-dichloro-2-hydroxybenzoic acid metabolite in animal matrices.

860.1360 Multiresidue Methods

According to FDA's PAM Volume I, Appendix II, dicamba is completely recovered using Section 402 E2 of Protocol B but is only partially recovered using Section 402 E1 of Protocol B. There are no multiresidue methods recovery data for the dicamba metabolites of concern (5-OH dicamba and DCSA), and these data are required. To fulfill this requirement, the registrants are required to follow the directions for the protocols found in PAM Vol. I, Appendix II under paragraph (d)(1) of OPPTS 860.1360 GLN, starting with the decision tree for multiresidue methods testing and the accompanying guidance found in the suggestions for producing quality data.

860.1380 Storage Stability

MRID 43245204 (Sugarcane (DP Barcodes D204488, D204809, and D209229; 7/14/97; L. Cheng)
MRID 43245205 (Sorghum) (DP Barcodes D204488, D204809, and D209229; 7/14/97; L. Cheng)
MRID 43245206 (Asparagus) (DP Barcodes D204488, D204809, and D209229; 7/14/97; L. Cheng)
MRID 43274501 (Wheat) (DP Barcodes D204488, D204809, and D209229; 7/14/97; L. Cheng)
MRID 43370701 (Grass forage and hay) (DP Barcode D207649, 3/11/96, L. Cheng)
MRID 43866601 (Corn) (DP Barcode D228703, 7/16/98, S. Chun)
MRID 43814102 (Soybean) (DP Barcodes D223283. ...; 7/29/96; S. Knizner, W. Dykstra, and C. Lewis)
MRID 46668101 (Ruminant) (DP Barcode 322842, 11/29/05, C. Olinger)

Plant commodities

The Dicamba (SRR) Registration Standard dated 6/30/89 noted disparity in the storage stability data from a few earlier study submissions and requested additional data. New storage stability data have subsequently been submitted, and many of these storage stability data were included in the submissions for field and processing studies to replace Craven data. The new data have all been reviewed and deemed adequate to satisfy reregistration requirements except for the requirement to submit data for sugarcane molasses. HED is requiring storage stability data for sugarcane molasses to validate the interval and conditions (64 days, <-1 °C) of samples from the submitted sugarcane processing study (MRID 43245204).

There are now adequate storage stability data for various representative crop commodities. These data indicate that residues of dicamba, 5-OH dicamba and DCSA are reasonably stable under frozen storage conditions at the maximum intervals tested. The data summarized below fulfill the reregistration requirements for storage stability data on plant commodities except for sugarcane molasses. For the purpose of tolerance reassessment, the maximum residues observed in the field and processing studies need not be adjusted or corrected for any decline in residues.

A storage stability study for field corn matrices (MRID 43866601) is available. In this study, residues of dicamba and 5-OH dicamba were found to be stable under frozen storage conditions in/on field corn forage, silage, grain, and fodder for up to 3 and 2 years, respectively. These data validate the storage conditions and intervals of samples collected from the most recent field corn trials. The HED review of these corn storage stability data concluded that the data may be translated to other cereal grains. The storage conditions and intervals of samples collected from residue field studies of various cereal grain crops follow. Wheat grain samples reviewed in conjunction with PP#4F3041 were stored frozen for 35-197 days (~1-7 months), and wheat straw samples were stored frozen for 51-220 days (~2-7 months). Barley forage samples were stored frozen for 29-149 days (~1-5 months), barley grain samples were stored frozen for 21-147 days (~1-5 months), barley hay samples were stored frozen for 40-160 days (~1-5 months), and barley straw samples were stored frozen for 27-177 days (~1-6 months).

A storage stability study for soybean matrices (MRID 43814102) has been submitted/reviewed. The results show that residues of dicamba and DCSA are stable under frozen storage conditions in/on soybean forage for up to 4 months and in refined oil for up to 3 months. Samples of soybeans and processed soybean fractions, collected from the field and processing studies, were stored frozen from 4-10 months prior to residue analysis.

In conjunction with the wheat field trials (MRID 43274501), the registrant conducted a storage stability study using wheat forage and hay. The data indicate that residues of dicamba and its 5-OH metabolite are stable in/on frozen wheat forage and hay for up to 258 and 283 days, respectively. Wheat forage and hay samples from the field study were stored at <-17 °C for 4-357 days prior to analysis; however, only 10 of the ~350 samples had a storage interval of >200 days.

In conjunction with the grass field trials (MRID 43370701), the registrant submitted data depicting the frozen storage stability of dicamba and its 5-OH metabolite in/on grass forage and hay. These data indicate that residues of dicamba and 5-OH dicamba are stable in/on frozen grass forage and hay for up to 314 and 320 days, respectively (10 months). Samples collected from this study were stored frozen for up to 13 months prior to residue analysis.

In conjunction with the sorghum processing study (MRID 43245205), the registrant submitted data depicting the frozen storage stability of dicamba and its 5-OH metabolite in/on sorghum grain. These data indicate that residues of dicamba and 5-OH dicamba are stable in/on frozen sorghum grain for up to 5 months and are adequate to support the storage interval and conditions of the grain and grain dust samples (up to 5 months, <-17 °C).

In conjunction with the asparagus field trial (MRID 43245206), the registrant submitted supporting storage stability data which indicate that residues of dicamba and DCSA are stable in/on asparagus for up to 104 days of frozen (<-12 °C) storage and that residues of 5-OH dicamba are stable for up to 119 days of frozen (<-12 °C) storage. Samples in the asparagus field trials (MRIDs 43245206 and 43245803) were stored frozen at <-12 °C for up to 95 days prior to analysis.

In conjunction with the sugarcane processing study (MRID 43245204), the registrant submitted supporting storage stability data which indicate that residues of dicamba and its hydroxy metabolite are stable in the refined white sugar of sugarcane stored frozen up to 60 days at <-1 °C. Confirmatory storage stability data reflecting storage interval of 64 days are required for sugarcane molasses.

Animal commodities

A storage stability study (MRID 46668101) for ruminant commodities has been submitted. Dicamba and its metabolite 3,6-dichloro-2-hydroxybenzoic acid are stable in ruminant muscle, fat, kidney, liver, and milk for at least 18 months. No additional storage stability data are required to support the existing livestock feeding studies.

860.1400 Water, Fish, and Irrigated Crops

There are no registered or proposed uses that are relevant to this guideline topic.

860.1460 Food Handling

There are no registered or proposed uses that are relevant to this guideline topic.

860.1480 Meat, Milk, Poultry, and Eggs

[redacted]

Maximum theoretical dietary burden (MTDB)

There are several livestock feed items associated with the crops which are being supported for reregistration. Following tolerance reassessment, the MTDBs of dicamba have been calculated as follows: 82 ppm for beef cattle; 482 ppm dairy cattle; 5.65ppm swine; and 5.2 ppm for poultry; see Tables 6 and 7. The feed items which contribute significantly to the dietary burdens for ruminants include grass forage/hay, aspirated grain fractions, and cereal grains.

Table 6. Calculation of Maximum Dietary Burdens of Dicamba to Livestock.				
Feedstuff	% Dry Matter [1]	% Diet [1]	Reassessed Tolerance (ppm)	Dietary Contribution (ppm) [2]
Beef Cattle				
Grass hay	88	20	250	56.82
Aspirated grain fractions	85	5	1000	58.82
Corn grain	88	60	0.1	0.07
Soybean Meal	82	15	10	1.83
TOTAL BURDEN	--	100	--	**117.54**
Dairy Cattle				
Grass forage	25	30	400	480.00
Undelinted Cotton Seed	88	10	5	0.57
Corn grain	88	50	0.1	0.06
Wheat grain	89	20	2.0	0.45
Soybean Meal	82	10	10	1.22
TOTAL BURDEN	--	100	--	**481.84**
Swine				
Sorghum grain	86	80	4.0	3.82
Soybean Meal	82	15	10	1.83
TOTAL BURDEN	--	100	--	**5.65**
Poultry				
Soybean seed	89	20	10	2.0
Sorghum grain	86	80	4.0	3.2
TOTAL BURDEN	--	100	--	**5.2**

[1] Table 1 (OPPTS Guideline 860.1000).
[2] Contribution = ([tolerance /% DM] x % diet) for beef and dairy cattle; contribution = (tolerance x % diet) for poultry and swine.

Ruminants

Established tolerance(s): Tolerances have been established under 40 CFR §180.227 (a)(2) for the combined residues of dicamba and its DCSA metabolite in the: (i) fat, meat, and meat byproducts of cattle, goat, hog, horse, and sheep at 0.2 ppm; (ii) kidney and liver of cattle, goat, hog, horse, and sheep at 1.5 ppm; and (iii) milk at 0.3 ppm.

Conclusions: The available ruminant feeding study (MRID 00079742), which was discussed in PP#3F2794 and re-summarized in the HED review (DP Barcodes D220430,... 5/2/96, F. Griffith) was conducted at 400 ppm. A new bovine feeding study was required. In 1998 the registrant, BASF, committed (DP Barcode D228703, 7/16/98, S. Chun) to conduct a bovine feeding study at a feeding level of 1000 ppm. The study has been reviewed (MRID 44891303) and is considered adequate. Modification of the tolerances are required at levels ranging from 0.2 ppm for fat to 25 ppm for kidney. No other ruminant feeding study data are required.

Discussion of the Data: Dicamba acid was administered via balling gun to five head of cattle for 28 days. Dosing was made at a nominal concentration of 1000 ppm in the feed. All but two of the animals were sacrificed within 2 hours of the final dose, but two animals were sacrificed five or ten days after the final dose to study the depuration of dicamba in livestock. Samples were analyzed using BASF Analytical Method Number AM-0938-0944-0, with some modifications for fat and cream samples. Acceptable method recoveries were obtained for all matrices. Samples were stored for an interval of demonstrated stability for dicamba and its metabolite 3,6 dichlorosalicylic acid. At sacrifice residues of dicamba and DCSA were detectable in all matrices at levels ranging from 0.4 ppm in muscle to 47 ppm in kidney. Residues in milk reached a plateau within a few days of dosing, with an approximate maximum of 0.2 ppm. Residues in milk dissipated to non-detectable levels within five days of dosing cessation, as observed in the depuration study.

Poultry

Established tolerance(s): No tolerances are established for the combined residues of dicamba and its DCSA metabolite in poultry eggs and meat.

Conclusions: A poultry feeding study with dicamba is not required based on the results of the submitted poultry metabolism study (MRID 43245202). In this study, the TRR levels in eggs, liver, muscle, and fat were all <0.004 ppm following dosing at 10 ppm (~1.9x the maximum dietary burden of 5.2 ppm) in the diet for four consecutive days. Residues in eggs reached a plateau after the first day of dosing (i.e., there was no accumulation with increasing days of dosing). HED does not anticipate the occurrence of quantifiable residues of dicamba or DCSA in poultry eggs and meat as a result of treating crops with poultry feed items at the maximum use patterns. Therefore, HED concludes that tolerances are not needed in poultry eggs and meat at this time but may be required if additional uses are registered in the future. A poultry feeding study (MRID 00148127) with dicamba, reflecting feeding rates equivalent to 2, 6, and 20 ppm in the diet, is available; these data were summarized in PP#3F2794 (8/15/85 memo, M. Firestone).

860.1500 Crop Field Trials

Residue studies that were generated by Craven Laboratories had been identified by HED, and a Data Call-In Notice was issued on 02/94 requesting end-use producer(s) of dicamba to conduct new field trials on barley, corn (field), sorghum, soybean, sugarcane, and wheat (D204754, 7/12/94, S. Funk). Several residue chemistry studies have been submitted and reviewed in response to the Dicamba DCI Notice. These Craven-replacement data along with those data for other crops which will be supported for reregistration were re-evaluated in this Residue Chemistry Chapter.

Legume Vegetables (Crop Group 6)

Soybean seed

MRID 43814101 (DP Barcodes D223283, ...7/29/96, S. Knizner, W. Dykstra, and C. Lewis)
MRID 44089307 (DP Barcode D228703, 7/16/98, S. Chun)

Established tolerance(s): A tolerance of 10 ppm has been established for the combined residues of dicamba and its two metabolites (5-OH dicamba and DCSA) in/on soybean seed [40 CFR §180.227 (a)(3)].

Uses to be supported: According to the Dicamba Master Use Profile (see Table 4), use of dicamba and its salts on soybeans will be supported at a maximum seasonal rate of 2.0 lb ae/A. In conjunction with PP#s 6F4604 and 4F3041 (DP Barcode D249098, 10/13/98, W. Donovan), the registrant has submitted a revised Section B specifying a 7-day PHI for soybeans.

Conclusions: There are adequate Craven replacement studies depicting magnitude of the regulated residues in/on soybean seed. Data from these submissions show that the highest total residues (dicamba + DCSA + 5-OH dicamba) were 3.74 ppm (MRID 43814101) and 8.13 ppm (MRID 44089307) in/on samples of soybean seed harvested 6-8 days following the last of a treatment schedule which includes a preplant application at 0.5 lb ae/A followed by a preharvest broadcast application at 2.0 lb ae/A for a total of 2.5 lb ae/A (1.25x the maximum rate listed in the Dicamba Master Use Profile). The available data indicate that the established tolerance of 10 ppm for soybean seed will not be exceeded when representative salt formulations of dicamba are applied at a slightly exaggerated total rate of 2.5 lb ae/A.

Discussion of data: The study reported in MRID 43814101 include data from 17 soybean trials conducted during the 1994 growing season in AR, GA, IL(2) , IN(2), IA(2), LA, MN(2), MS, MO(2), NE, OH, and TN. The number and locations of soybean trials from this study along with those conducted in MRID 44089307 are adequate to satisfy GLN 860.1500 with regard to geographic representation of data. Two types of treatment patterns were evaluated using the DMA salt formulation of dicamba: (i) a single preplant (14 days prior to planting) broadcast application at 0.5 lb ae/A (0.25x); and (ii) preplant treatment at 0.5 lb ae/A plus preharvest broadcast application at 2.0 lb ae/A for a total of 2.5 lb ae/A (1.25x). In addition, four side-by-side trials were conducted in IA, IL, IN, and MN with the DGA, DMA, and Na salt formulations of dicamba at the same application rates and harvest intervals; soybeans seeds were harvested 6-8 days following posttreatment. Injury (e.g., delayed emergence, delayed opening of cotyledons, and reduced stand) was observed in the treated plots after the preplant treatment.

The harvested soybean seed samples were analyzed using GC Method No. AM-0941-1094-0 with a limit of detection of 0.01 ppm for each residue in all matrices. In this method, residues of dicamba and DCSA were quantitated by GC using a Ni electron capture detector (ECD) whereas residues of 5-OH dicamba were quantitated separately by GC/ECD. This method was validated at fortification range of 0.01-0.5 ppm. The method recoveries were well within the acceptable range. Soybean seed samples were stored frozen for a maximum interval of 220 days (~7 months) prior to residue analysis. There are adequate storage stability data to support this interval.

The results show that following a single preplant broadcast treatment (14 days prior to planting) of the DMA salt of dicamba at 0.5 lb ae/A (0.25x), residues of dicamba, DCSA, and 5-OH-dicamba were each <0.01 ppm in/on soybean seeds. Following preplant plus preharvest treatments for a total of 2.5 lb ae/A (1.25x), individual residues in/on soybean seed samples harvested at a 6-8 day PHI were 0.072-3.301 ppm for dicamba *per se*, <0.01-0.115 ppm for DCSA, and <0.01-0.357 ppm for 5-OH dicamba. The HAFT combined residues in/on treated soybean seed from this study was 3.6 ppm. In side-by-side trials using the DMA, DGA, and Na salts of dicamba, residue levels did not vary according to the formulation used.

MRID 44089307: Six soybean field trials were conducted in IA, IN, IL(2), MO, and NC using the DMA salt formulation of dicamba. Two types of treatments were used. Treatment A (PRPR1) consisted of a preplant broadcast application of 0.5 lb ae/A (0.25x), made to the soil surface 14 days before planting soybean. Treatment B (POPO1) consisted of Treatment A plus a preharvest broadcast application of 2.0 lb ae/A for a total of 2.5 lb ae/A (1.25x), made 7 days before normal harvest. Only grain samples were collected from Treatment B.

Samples were analyzed for dicamba, its 5-OH dicamba metabolite, and its DCSA metabolite using a GC/ECD method (AM-0941-1094-0). The LOQ for this method is 0.02 ppm. The method was validated over a range of 0.02-1.0 ppm for soybean commodities. The overall average corrected recovery for all matrices (hay, grain, and forage) was 98% ± 13 (n=17) for dicamba, 93% ± 18 (n=16) for DCSA, and 90% ± 11 (n=15) for 5-OH dicamba. HED review of this study noted that residues in soybean seed were found well above the range of the method validation, and therefore, requested additional method validation at a spike level of up to 10 ppm in soybean seed. Total storage interval, between harvest and analysis, for all samples was 31-104 days (~1-3 months). This interval is supported by adequate storage stability data.

The results show that following preplant broadcast application at 0.25x, residues of dicamba, DCSA, and 5-OH dicamba were <0.01 ppm each in/on soybean seed. Total residues (dicamba + DCSA + 5-OH dicamba) in/on soybean seed from Treatment A were calculated at <0.015 ppm. Following a combination of preplant + preharvest applications at 1.25x, the ranges of individual residues in/on soybean seed harvested at a 7-day PHI were: 0.027-8.1 ppm for dicamba, <0.01-0.033 ppm for DCSA, and <0.01-0.011ppm for 5-OH dicamba. Total residues (dicamba + DCSA + 5-OH dicamba) in/on soybean seed which received preplant plus preharvest treatments were 0.037-8.13 ppm. The HAFT combined residues in/on treated soybean seed from this study was 7.44 ppm.

Foliage of Legume Vegetables (Crop Group 7)

Soybean forage and hay

MRID 43814101 (DP Barcodes D223283, ...7/29/96, S. Knizner, W. Dykstra, and C. Lewis)
MRID 44089307 (DP Barcode D228703, 7/16/98, S. Chun)

Established tolerance(s): No dicamba tolerances are currently established on soybean forage and hay.

Uses to be supported: According to the Dicamba Master Use Profile (see Table 4), use of dicamba and its salts on soybeans will be supported at a maximum seasonal rate of 2.0 lb ae/A.

Conclusions: There are Craven replacement studies (MRIDs 43814101 and 44089307) depicting magnitude of the regulated residues in/on soybean forage and hay. Data from MRID 43814101 show that following one preplant application of the DMA salt formulation of dicamba at 0.5 lb ae/A (0.25x the maximum rate listed in the Dicamba Master Use Profile), the total residues (dicamba, DCSA, and 5-OH-dicamba) ranged <0.03-<0.097 ppm for soybean forage and <0.03-<0.04 ppm for soybean hay. In another submission (MRID 44089307), it was reported that the total residues in/on samples treated similarly were 0.015-0.062 ppm for soybean forage and <0.015 ppm for soybean hay.

It is the current Agency policy to allow label restrictions on the feeding/grazing of livestock animals on soybean forage and hay, thus, precluding the need for residue data and tolerances for these soybean commodities. HED defers to RD for verifying whether such restrictions exist on product labels. If such restrictions appear on the labels, then residue data and tolerances for soybean forage and hay are not necessary. If no such restrictions appear on the labels, then the registrants are required to propose tolerances for soybean forage and hay at 0.1 ppm each. Concomitant with these tolerance proposals, the registrants are required to propose a maximum seasonal rate of 0.5 lb ae/A for preplant application on soybean grown for forage and hay only.

Discussion of data: The study reported in MRID 43814101 include data from 17 soybean trials conducted during the 1994 growing season in AR, GA, IL(2) , IN(2), IA(2), LA, MN(2), MS, MO(2), NE, OH, and TN. The number and locations of soybean trials from this study along with those conducted in MRID 44089307 are adequate to satisfy GLN 860.1500 with regard to geographic representation of data. Two types of treatment patterns were evaluated using the DMA salt formulation of dicamba: (i) a single preplant (14 days prior to planting) broadcast application at 0.5 lb ae/A (0.25x); and (ii) preplant treatment at 0.5 lb ae/A plus preharvest broadcast application at 2.0 lb ae/A for a total of 2.5 lb ae/A (1.25x). In addition, four side-by-side trials were conducted in IA, IL, IN, and MN with the DGA, DMA, and Na salt formulations of dicamba at the same application rates and harvest intervals. Soybean forage and hay were collected from plants receiving only preplant treatment. Only soybeans seeds were collected from plants which received both preplant and preharvest treatments. Samples were analyzed using GC Method No. AM-0941-1094-0 with a limit of detection of 0.01 ppm for each residue in all matrices. In this method, residues of dicamba and DCSA were quantitated by GC using a Ni

ECD whereas residues of 5-OH dicamba were quantitated separately by GC/ECD. This method was validated at fortification range of 0.01-0.5 ppm. The method recoveries were well within the acceptable range. Samples were stored frozen for maximum intervals of 175-316 days (~6-10 months) for forage and 140-230 days (~5-8 months) for hay prior to residue analysis. There are adequate storage stability data to support these intervals. The results show that following a single preplant broadcast treatment (14 days prior to planting) of the DMA salt of dicamba at 0.5 lb ae/A (0.25x), the total residues (dicamba, DCSA, and 5-OH-dicamba) ranged <0.03-<0.097 ppm for soybean forage and <0.03-<0.04 ppm for soybean hay. In side-by-side trials using the DMA, DGA, and Na salts of dicamba, residue levels did not vary according to the formulation used.

MRID 44089307: Six soybean field trials were conducted in IA, IN, IL(2), MO, and NC using the DMA salt formulation of dicamba. Two types of treatments were used. Treatment A (PRPR1) consisted of a preplant broadcast application of 0.5 lb ae/A (0.25x), made to the soil surface 14 days before planting soybean. Treatment B (POPO1) consisted of Treatment A plus a preharvest broadcast application of 2.0 lb ae/A for a total of 2.5 lb ae/A (1.25x), made 7 days before normal harvest. Forage and hay samples were collected from Treatment A. Samples were analyzed for dicamba, its 5-OH dicamba metabolite, and its DCSA metabolite using a GC/ECD method (AM-0941-1094-0). The LOQ for this method is 0.02 ppm. The method was validated over a range of 0.02-1.0 ppm for soybean commodities. The overall average corrected recovery for all matrices (hay, grain, and forage) was 98% ± 13 (n=17) for dicamba, 93% ± 18 (n=16) for DCSA, and 90% ± 11 (n=15) for 5-OH dicamba. Total storage interval, between harvest and analysis, for all samples was 31-104 days (~1-3 months). This interval is supported by adequate storage stability data. The results show that the total residues (dicamba + DCSA + 5-OH dicamba) were 0.015-0.062 ppm in/on soybean forage and <0.015 ppm in/on soybean hay samples following a preplant treatment at 0.5 lb ae/A; the PHI was not specified.

Cereal Grains (Crop Group 15)

The adequacy of available residue data for the individual cereal grains, which are being supported for reregistration, are detailed below.

Barley grain

MRID 44089304 (DP Barcode D228703, 7/16/98, S. Chun)

Established tolerance(s): A tolerance of 6.0 ppm has been established for the combined residues of dicamba and its metabolite (5-OH dicamba) in/on barley grain [40 CFR §180.227 (a)(1)].

Uses to be supported: According to the Dicamba Master Use Profile (see Table 4), the DMA, Na, DGA, and IPA salts will be supported on barley at a maximum single application rate of 0.25 lb ae/A and a maximum yearly rate of 0.38 lb ae/A. In conjunction with PP#s 6F4604 and 4F3041 (DP Barcode D249098, 10/13/98, W. Donovan), the registrant has submitted a revised Section B specifying a 7-day PHI for barley.

Corn, field, grain

MRID 44089303 (DP Barcode D228703, 7/16/98, S. Chun)

Established tolerance(s): A tolerance of 0.5 ppm has been established for the combined residues of dicamba and its metabolite (5-OH dicamba) in/on "corn, grain" [40 CFR §180.227 (a)(1)].

Uses to be supported: According to the Dicamba Master Use Profile (see Table 4), the DMA, Na, DGA, and K salts of dicamba will be supported on field corn at a maximum single application rate of 0.5 lb ae/A and a maximum yearly rate of 0.75 lb ae/A.

Conclusions: There are Craven replacement data (MRID 44089303) depicting residues of dicamba and 5-OH dicamba in/on field corn grain. These data represent not only the application specifically listed for corn, but also the use on fallow agricultural soils at 2 lb ae/A for a total rate of 2.75 lb ae/A. The combined residues of dicamba and 5-OH dicamba ranged from <0.01 to 0.015 ppm in/on field corn grain samples harvested 69-123 days following the last of three sequential treatments (2.0 lb ae/A + 0.5 lb ae/A + 0.25 lb ae/A) of representative dicamba salt formulations for a total of 2.75 lb ae/A. No residues of dicamba *per se* were detected in/on any of the treated grain samples from any of the trial locations. Residues of 5-OH dicamba ranged from <0.01 to 0.015 ppm. The data support reduction of the tolerance to 0.1 ppm.

Discussion of data: The submission for MRID 44089303 includes data from a total of 20 field corn trials conducted between 1994-1995 in 16 states: IA(2), IL(2), IN, KS, KY, MN(2), MI, MO, NE(2), NC, ND, OH, OK, PA, SD and WI. These states cover EPA regions I (1), II (1), V (17), and VI (1). Geographic representation of data is adequate since the number and location of field corn trials is in accordance with Tables 1 and 5 of GLN 860.1500. The DMA salt formulation was applied in 12 trial locations. Side-by-side trials with the DMA, DGA, and Na salt formulations of dicamba were conducted at 8 trial locations to compare the residues found from use of the different salt formulations.

Three broadcast applications of dicamba were used on each treated plot at each site. The first application at 2.0 lb ae/A was made to crop stubble, fallow or bare ground in the fall of 1994 prior to ground freeze, with subsequent planting of field corn in the spring of 1995. The second application at 0.5 lb ae/A was made in the spring to 8-inch tall field corn. The last application at 0.25 lb ae/A was made in the spring or summer to 36-inch tall field corn. The total applied rate was 2.75 lb ae/A (3.7x the maximum yearly rate listed in the Dicamba Master Use Profile). Samples of field corn grain were collected at a PHI range of 66-123 days.

Samples of field corn grain were analyzed for dicamba and 5-OH dicamba using a GC/ECD method (Sandoz Method AM-0691B-0593-3) with a limit of detection of 0.01 ppm. The adequacy of the method for data collection was validated by separately fortifying grain control samples with dicamba and 5-OH dicamba at the following levels: 0.010, 0.10, 0.50, and 1.0 ppm. Method recoveries were within the acceptable range. Information pertaining to sample storage intervals was not specified in the HED review. However, there are adequate storage

<u>Conclusions</u>: There are Craven replacement data (MRID 44089304) depicting residues of dicamba and 5-OH dicamba in/on barley grain at application rates of 0.125 or 0.375 lb ae/A. The combined residues of dicamba and 5-OH dicamba ranged 0.021-1.203 ppm in/on samples of barley grain harvested 7 days following one broadcast application made to the crop prior to first joint stage using representative dicamba salt formulations at 0.125 lb ae/A (1x). Other data points indicate that the combined residues were 0.671-5.063 ppm in/on grain samples harvested 7 days following the last of two treatments (with the first made prior to joint stage followed by a preharvest treatment) for a total of 0.375 lb ae/A (1x). The existing tolerance of 6.0 ppm for barley grain is adequate and no additional data are required.

<u>Discussion of data</u>: The submission for MRID 44089304 depicts magnitude of the residues of dicamba and 5-OH dicamba in/on barley grain. Eleven field trials were conducted in CA, ID, MN, MT, ND(2), OR, PA, SD(2), and UT. A field trial was also conducted in WY but no samples were collected from this trial site. Geographic representation of data is adequate since the number and location of barley trials is in accordance with Table 1 of GLN 860.1500. The barley field trials were conducted using the following salt formulations of dicamba: DMA, DGA, and Na

Two types of treatments were used. Treatment A (POPO1) consisted of one broadcast application at 0.125 lb ae/A, made to the crop immediately prior to first joint stage. Treatment B (POPO2) consisted of Treatment A plus a preharvest broadcast application at 0.25 lb ae/A, made 7 days before normal harvest. The DMA salt formulation of dicamba was applied in five trial locations. Side-by-side trials with DMA, DGA, and Na salt formulations of dicamba were conducted at four different trial locations. Samples were analyzed for dicamba and 5-OH dicamba using a GC/ECD method (Sandoz Method AM-0691B-0593-3) with an LOQ of 0.01 ppm. The adequacy of the method for data collection was validated by fortifying grain control samples with dicamba and 5-OH dicamba at 0.01-1.0 ppm. The average method recoveries for the field trials were acceptable (>70%) for all barley commodities. However, the HED review noted that the method was not validated over an acceptable range since residue levels in barley grain were found well above the ranges of the method validation. The HED review, thus, requested additional method validation at a spike level of up to 6.0 ppm for barley grain. Barley grain samples were stored frozen for 21-147 days (~1-5 months) prior to residue analysis. There are adequate storage stability data available for field corn matrices which may be translated to barley grain.

The results indicate that the total residues (dicamba + 5-OH dicamba) in/on all treated barley grain samples ranged 0.021-1.203 ppm for Treatment A (1x) and 0.671-5.063 ppm for Treatment B (1x). Statistical analysis performed by the registrant suggested that there was no significant difference in the magnitude of the residue samples based on formulation.

stability data which indicate that dicamba and 5-OH dicamba residues are stable in/on corn matrices under frozen storage conditions for up to 3 and 2 years, respectively.

The results indicate that the total residues (dicamba + 5-OH dicamba) in/on all treated grain samples ranged from <0.01 to 0.015 ppm. No residues of dicamba were detected in any of the treated grain samples from any of the trial locations. Residues of 5-OH dicamba ranged from <0.01 to 0.015 ppm. Analysis of Variance (ANOVA) statistical analysis was performed on the data collected from the 8 locations where the DMA, DGA, and Na dicamba salt formulations were used. The results indicate that the difference in the magnitude of the residues observed in grain was influenced by the difference in the trial locations and not by the difference in the dicamba salt formulations.

Corn, pop, grain

Established tolerance(s): A tolerance of 0.5 ppm has been established for the combined residues of dicamba and its metabolite (5-OH dicamba) in/on "corn, grain" [40 CFR §180.227 (a)(1)].

Uses to be supported: According to the Dicamba Master Use Profile (see Table 4), the DMA, Na, DGA, and K salts of dicamba will be supported on pop corn at a maximum single application rate of 0.5 lb ae/A and a maximum yearly rate of 0.75 lb ae/A.

Conclusions: There are no residue data on pop corn grain reflecting the maximum rate of 0.75 lb ae/A which is the maximum single/yearly application rate the registrants wish to support for pop corn. HED will allow the translation of available data for field corn grain to pop corn grain since the Dicamba Master Use Profile indicates that the application rate of the two crops is identical. However, any label revision for field corn should also be made for pop corn.

Millet, proso, grain

Established tolerance(s): A tolerance of 0.5 ppm has been established for the combined residues of dicamba and its metabolite (5-OH dicamba) in/on proso millet grain [40 CFR §180.227 (a)(1)].

Uses to be supported: According to the Dicamba Master Use Profile (see Table 4), the DMA salt of dicamba will be supported on proso millet at a maximum single application rate of 0.125 lb ae/A and a maximum yearly rate of 0.125 lb ae/A.

Conclusions: The current RAC tolerance level of 0.5 ppm was established through an IR-4 petition (PP#9E2166) based on limited residue data generated on proso millet from two field trials conducted in NE at 0.125 lb ae/A (0.125x). Consistent with the recommendation of Dicamba (SRR) Registration Standard dated 6/30/89, HED will allow the translation of available data for wheat grain to proso millet grain since the Dicamba Master Use Profile indicates that the application rate for wheat is higher. Based on the wheat grain data, HED recommends that the tolerance be increased to 2.0 ppm.

Oat grain

Established tolerance(s): A tolerance of 0.5 ppm has been established for the combined residues of dicamba and its metabolite (5-OH dicamba) in/on oat grain [40 CFR §180.227 (a)(1)].

Uses to be supported: According to the Dicamba Master Use Profile (see Table 4), the DMA, Na, and DGA salts of dicamba will be supported on oats at a maximum single application rate of 0.125 lb ae/A and a maximum yearly rate of 1.0 lb ae/A.

Conclusions: There are no residue data on oat grain reflecting the maximum rate of 1.0 lb ae/A which is the maximum single/yearly application rate the registrants wish to support for oats. The current RAC tolerance level of 0.5 ppm was established through PP#8F0666 based on limited data generated on spring-seeded oats from trials conducted in VA at application rates of 0.125 to 0.25 lb ae/A (0.125x to 0.25x). Consistent with the recommendation of Dicamba (SRR) Registration Standard dated 6/30/89, HED will allow the translation of available and requested data for wheat grain to oat grain since the Dicamba Master Use Profile indicates that the application rate of the two crops is identical. Any label revision for wheat should also be made for oats. Concurrently, any adjustment to the wheat grain tolerance should also be applied as necessary to the oat grain tolerance.

Rye grain

Established tolerance(s): No dicamba tolerance has been established for rye grain.

Uses to be supported: According to the Dicamba Master Use Profile (see Table 4), the DMA salt of dicamba will be supported on rye at a maximum single application rate of 0.5 lb ae/A and a maximum yearly rate of 1.0 lb ae/A.

Conclusions: There are no available residue data on rye grain. HED will allow the translation of available and requested data for wheat grain to rye grain since the Dicamba Master Use Profile indicates that the yearly application rate of the two crops is identical. Any label revision for wheat should also be made for rye. Concurrently, any adjustment to the wheat grain tolerance should also be applied as necessary to the rye grain tolerance that needs to be established.

Sorghum grain

MRID 43245203 (DP Barcodes D204488, D204809, and D209229; 7/14/97; L. Cheng)
MRID 44089306 (DP Barcodes D304019, D306687-D306690: in review, C. Olinger)

Established tolerance(s): A tolerance of 3.0 ppm has been established for the combined residues of dicamba and its metabolite (5-OH dicamba) in/on sorghum grain [40 CFR §180.227 (a)(1)].

Uses to be supported: According to the Dicamba Master Use Profile (see Table 4), all salts of dicamba will be supported on sorghum at a maximum single application rate of 0.2748 lb ae/A and a maximum yearly rate of 0.5 lb ae/A.

Conclusions: The registrant has submitted Craven replacement data depicting residues of dicamba and 5-OH dicamba in/on sorghum grain. These data have been reviewed and deemed adequate to satisfy reregistration requirements pending label revisions and tolerance adjustment. The submitted data show that the maximum combined residues of dicamba and its 5-OH metabolite were 2.73 ppm (MRID 43245203) and 3.164 ppm (MRID 44089306) in/on sorghum grain harvested 30-42 days following the last of a treatment schedule which includes one post directed application made under the crop canopy at 0.25 lb ae/A followed by a second broadcast application made at soft dough stage at 0.25 lb ae/A for a total rate of 0.5 lb ae/A (1x the maximum rate listed in the Dicamba Master Use Profile). These data suggest that the established tolerance for sorghum grain may be too low. Based on the reviewed data, HED is recommending tolerance level of 4.0 ppm for sorghum grain concomitant with label revision to specify a 30-day PHI.

Discussion of data: The submission for MRID 43245203 contain data depicting residues of dicamba and its 5-OH metabolite in/on sorghum grain. A total of 40 field trials were conducted in KS(8), MO(8), NE(8), OK(8), and TX(8) using four salt formulations of dicamba: the Na, DGA, K, and DMA salts. Geographic representation of data is more than adequate when the trials conducted from this study along with those conducted from MRID 44089306 are considered. At each test site, one or two applications of each of the four dicamba formulations were made at 0.25 lb ae/A/application for total rates of 0.25 lb ae/A (~0.5x) and 0.5 lb ae/A (1x). Applications were made in 19.6-21.5 GPA using ground equipment. The 0.5x plots were treated when the plants were 15" tall using a broadcast application sprayed directly under the canopy (20-109 PTI). The 1x plots received an additional application of 0.25 lb ae/A when the crop was at the soft dough stage (30-42 PTI).

Sorghum grain samples were analyzed for residues of dicamba and 5-OH dicamba using a GC/ECD method (Method AM-0691B) with a limit of detection of 0.01 ppm for each analyte. The adequacy of the method for data collection was validated by fortifying untreated grain samples with dicamba and 5-OH dicamba at 0.01-0.1 ppm. Method recoveries were within the acceptable range. Samples were stored frozen at <-17 °C for 28-160 days (~1-5 months) prior to analysis. There are adequate storage stability data for sorghum grain to support sample storage conditions and intervals.

The results show that the combined residues of dicamba and its 5-OH metabolite were <0.02-0.184 ppm in/on 18 grain samples harvested 81-109 days following a single postemergence application at 0.25 lb ae/A (0.5x). Following two applications for a seasonal total of 0.5 lb ae/A (1x), the maximum combined residues were 2.73 ppm in/on 20 grain samples collected at PHIs of 30-42 days.

MRID 44089306: A total of seven sorghum trials were conducted in Regions 2 (NC; 1 trial), 4 (LA; 1 trial), 5 (IL and KS; 2 trials); 6 (OK; 1 trial), 7 (NE; 1 trial), and 8 (TX; 1 trial) during the 1995 growing season. The DMA salt of dicamba was the test formulation used in all trials. At each field trial site, two separate plots were treated with either a single post directed spray application made under the crop canopy of 15-inch tall sorghum plants at a rate of 0.25 lb ae/A (0.5x) or two applications (one post directed application followed by a second broadcast application made at soft dough stage) at 0.25 lb ae/A/application, with a 44- to 65-day retreatment interval, for a total rate of 0.5 lb ae/A (1x). Applications were made in 10-36 gal/A of water using ground equipment. Sorghum grain was collected from 1x-treated sites at PHIs of 30- to 34-days.

Samples were analyzed for residues of dicamba and its 5-OH metabolite using GC/ECD method AM-0691B-0593-3 with a validated LOQ of 0.02 ppm for each analyte. The method is adequate for data collection based on acceptable concurrent method recovery data. The grain samples were stored frozen for 99 days (3.3 months) prior to residue analysis. There are adequate storage stability data for sorghum grain to support sample storage conditions and intervals.

The results show that the maximum combined residues of dicamba and its 5-OH metabolite were 0.174 ppm in/on sorghum grain harvested 74-88 days following a single post directed spray application at 0.25 lb ae/A (0.5x). The maximum combined residues were 3.164 ppm in/on sorghum grain harvested 30-34 days following the last of two applications for a total rate of 0.5 lb ae/A (1x).

Wheat grain

MRID 44089305 (DP Barcode D228703, 7/16/98, S. Chun)

Established tolerance(s): A tolerance of 2.0 ppm has been established for the combined residues of dicamba and its metabolite (5-OH dicamba) in/on wheat grain [40 CFR §180.227 (a)(1)].

Uses to be supported: According to the Dicamba Master Use Profile (see Table 4), the DMA, Na, DGA, and IPA salts of dicamba will be supported on wheat at a maximum single application rate of 0.5 lb ae/A and a maximum yearly rate of 1.0 lb ae/A. In conjunction with PP#s 6F4604 and 4F3041 (DP Barcode D249098, 10/13/98, W. Donovan), the registrant has submitted a revised Section B specifying a 7-day PHI for wheat.

Conclusions: There are Craven replacement data (MRID 44089305) depicting residues of dicamba and 5-OH dicamba in/on wheat grain. These data, however, do not support the maximum seasonal rate of 1.0 lb ae/A that is listed in the Dicamba Master Use Profile because the wheat trials were conducted at application rates of 0.25 or 0.5 lb ae/A. The combined residues of dicamba and 5-OH dicamba ranged from <0.01 to 0.15 ppm in/on samples of wheat grain harvested 63-125 days following one spring broadcast application of representative dicamba salt formulations at 0.25 lb ae/A (0.5x). The combined residues ranged from 0.039 to 1.4 ppm in/on grain samples harvested 6-12 days following the last of two treatments for a total of 0.5 lb ae/A (0.5x).

For the purpose of reregistration, the registrants are required to submit a complete set of residue data on wheat grain reflecting a maximum seasonal rate of 1.0 lb ae/A. Alternatively, the registrants may rely on the available data provided they are willing to revise product labels for consistency with the reviewed data. If the registrants elect to choose the latter option, then they will be required to revise product labels to specify a maximum seasonal rate of 0.5 lb ae/A. The existing tolerance of 2.0 ppm for wheat grain will be considered adequate *if* the registrants elect to revise product labels.

Discussion of data: The submission for MRID 44089305 depicts magnitude of the residues of dicamba and 5-OH dicamba in/on wheat grain. A total of 20 field trials were conducted during the 1995 growing season in 16 states: CO(2), ID, IL, KS(2), MN, MO, MS, MT(2), NE, NM, NC, ND, OH, OK(2), TX, and WY. These states cover EPA regions II (1), IV (1), V(5), VI (1), VII (5), VIII (6), and XI (1). Geographic representation of data is adequate since the number and location of wheat trials is in accordance with Tables 1 and 5 of GLN 860.1500. The wheat field trials were conducted using the following salt formulations of dicamba: DMA, DGA, and Na.

Two treatment patterns, designated as A and B, were employed in this study. Treatment A consisted of a spring broadcast application at 0.25 lb ae/A (0.25x) made to the crop immediately prior to first joint (POPO1). Treatment B consisted of Treatment A plus a preharvest broadcast application at 0.25 lb ae/A, made 7 days before harvest (POPO2) for a total of 0.5 lb ae/A (0.5x). The DMA salt formulation of dicamba was applied in 10 trial locations. Side-by-side trials with the DMA, DGA, and Na salt formulations of dicamba were conducted at four trial locations to compare the residues found from use of the different salt formulations.

Samples were analyzed for dicamba and 5-OH dicamba using a GC/ECD method (Sandoz Method AM-0691B-0593-3) with a limit of detection of 0.01 ppm. The adequacy of the method for data collection was validated by fortifying untreated grain samples with dicamba and 5-OH dicamba at 0.010, 0.020, 0.10, and 1.0 ppm. Method recoveries were within the acceptable range. Wheat grain samples were stored frozen for 35-197 days (~1-7 months) prior to residue analysis. There are adequate storage stability data available for field corn matrices which may be translated to wheat grain.

The results indicate that the total residues (dicamba + 5-OH dicamba) in/on all treated grain samples ranged <0.01-0.15 ppm for Treatment A (0.25x) and 0.039-1.4 ppm for Treatment B (0.5x). Analysis of Variance (ANOVA) statistical analysis was performed on the data collected from the four locations where the DMA, DGA, and Na dicamba salt formulations were used. The results indicate that the difference in the magnitude of the residues observed in grain was influenced by the difference in the trial locations and not by the differences in the dicamba salt formulations.

Forage, Fodder, and Straw of Cereal Grains (Crop Group 16)

Barley hay and straw

MRID 44089304 (DP Barcode D228703, 7/16/98, S. Chun)

Established tolerance(s): Tolerances of 2.0 ppm and 15.0 ppm have been established for the combined residues of dicamba and its metabolite (5-OH dicamba) in/on barley hay and straw, respectively [40 CFR §180.227 (a)(1)].

Uses to be supported: According to the Dicamba Master Use Profile (see Table 4), the DMA, Na, DGA, and IPA salts of dicamba will be supported on barley at a maximum single application rate of 0.25 lb ae/A and a maximum yearly rate of 0.38 lb ae/A.

Conclusions: There are Craven replacement data (MRID 44089304) conducted at application rates of 0.125 or 0.375 lb ae/A. The combined residues of dicamba and 5-OH dicamba were <0.02-1.876 ppm in/on samples of barley hay harvested 7 days following one broadcast application made to the crop prior to first joint stage using representative dicamba salt formulations at 0.125 lb ae/A (0.5x). The combined residues were 0.388-10.519 ppm in/on barley straw samples harvested 7 days following the last of two treatments (with the first made prior to joint stage followed by a preharvest treatment) for a total of 0.375 lb ae/A (1x). The existing tolerances of 2.0 ppm and 15.0 ppm for barley hay and straw, respectively, are adequate.

Discussion of data: The submission for MRID 44089304 depicts magnitude of the residues of dicamba and 5-OH dicamba in/on barley hay and straw. [It is noted that this study also included data for barley forage which are not presented herein because forage is not a significant commodity of barley as per Table 1 of GLN 860.1000.] Eleven field trials were conducted in CA, ID, MN, MT, ND(2), OR, PA, SD(2), and UT. A field trial was also conducted in WY but no samples were collected from this trial site. Geographic representation of data is adequate as the number and location of barley trials is in accordance with Table 1 of GLN 860.1500. The barley field trials were conducted using the following salt formulations of dicamba: DMA, DGA, and Na.

Two types of treatments were used. Treatment A (POPO1) consisted of one broadcast application at 0.125 lb ae/A, made to the crop immediately prior to first joint stage. Treatment B (POPO2) consisted of Treatment A plus a preharvest broadcast application at 0.25 lb ae/A, made 7 days before normal harvest. The DMA salt formulation of dicamba was applied in five trial locations. Side-by-side trials with DMA, DGA, and Na salt formulations of dicamba were conducted at four different trial locations. Samples were analyzed for dicamba and 5-OH dicamba using a GC/ECD method (Sandoz Method AM-0691B-0593-3) with an LOQ of 0.01 ppm. The adequacy of the method for data collection was validated by fortifying untreated hay and straw samples with dicamba and 5-OH dicamba at 0.01-4.0 ppm. The average method recoveries for the field trials were acceptable (>70%) for all barley commodities. However, the HED review noted that the method was not validated over an acceptable range since residue levels in barley straw were found well above the ranges of the method validation. The HED review, thus, requested additional method validation at a spike level of up to 15 ppm for barley straw. Barley hay samples were stored frozen for 40-160 days (~1-5 months), and barley straw samples were stored frozen for 27-177 days (~1-6 months) prior to residue analysis. There are adequate storage stability data available for field corn matrices which may be translated to barley hay and straw

The results of Treatment A indicate that residues of dicamba *per se* in/on barley hay and straw were <0.01-1.046 ppm and < 0.01-0.251 ppm, respectively. Residues of 5-OH dicamba ranged as follows: <0.01-0.830 ppm in/on barley hay and <0.01-0.375 ppm in/on barley straw. The total residue levels (dicamba + 5-OH dicamba) were <0.02-1.876 ppm in/on barley hay and <0.02-0.626 ppm in/on barley straw.

The results of Treatment B indicate that the residues of dicamba *per se* were 0.331-10.466 ppm in/on barley straw. The residue levels of 5-OH dicamba were <0.01-2.058 ppm in/on barley straw. The total residue levels (dicamba + 5-OH dicamba) were 0.388-10.519 ppm in/on barley straw. The statistical analysis performed by the registrant indicated that there was no significant difference in the magnitude of the residue samples based on formulation.

Corn, field, forage and stover

MRID 44089303 (DP Barcode D228703, 7/16/98, S. Chun)

Established tolerance(s): A tolerance of 3.0 ppm has been established for the combined residues of dicamba and its metabolite (5-OH dicamba) in/on field corn forage and field corn stover [40 CFR §180.227 (a)(1)]. A generic tolerance of 0.5 ppm is also established for the combined residues of dicamba and its metabolite (5-OH dicamba) in/on "corn forage" and "corn stover" [40 CFR §180.227 (a)(1)].

Uses to be supported: According to the Dicamba Master Use Profile (see Table 4), the DMA, Na, DGA, and K salts of dicamba will be supported on field corn at a maximum single application rate of 0.5 lb ae/A and a maximum yearly rate of 0.75 lb ae/A.

Conclusions: There are Craven replacement data (MRID 44089303) depicting residues of dicamba and 5-OH dicamba in/on field corn forage and fodder (stover). These data represent not only the application specifically listed for corn, but also the use on fallow agricultural soils at 2 lb ae/A for a total rate of 2.75 lb ae/A. The combined residues of dicamba and 5-OH dicamba ranged from <0.01 to 2.27 ppm in/on field corn forage harvested 39-71 days following the last of three sequential treatments (2.0 + 0.5 lb + 0.25 lb ae/A) of crop using representative dicamba salt formulations for a total of 2.75 lb ae/A. The combined residues ranged from <0.01 to 2.45 ppm in/on field corn fodder harvested 66-123 days following same sequential treatments. The existing tolerances of 3.0 ppm for field corn forage and fodder are adequate.

Discussion of data: The submission for MRID 44089303 includes data from a total of 20 field corn trials conducted between 1994-1995 in 16 states: IA(2), IL(2), IN, KS, KY, MN(2), MI, MO, NE(2), NC, ND, OH, OK, PA, SD and WI. These states cover EPA regions I (1), II (1), V (17), and VI (1). Geographic representation of data is adequate since the number and location of field corn trials is in accordance with Tables 1 and 5 of GLN 860.1500. The DMA salt formulation was applied in 12 trial locations. Side-by-side trials with the DMA, DGA, and Na salt formulations of dicamba were conducted at 8 trial locations to compare the residues found from use of the different salt formulations.

Three broadcast applications of dicamba were used on each treated plot at each site. The first application at 2.0 lb ae/A was made to crop stubble, fallow or bare ground in the fall of 1994 prior to ground freeze, with subsequent planting of field corn in the spring of 1995. The second application at 0.5 lb ae/A was made in the spring to 8-inch tall field corn. The last application at 0.25 lb ae/A was made in the spring or summer to 36-inch tall field corn. The total applied rate was 2.75 lb ae/A (3.7x the maximum yearly rate listed in the Dicamba Master Use Profile). Samples of field corn forage were collected at a PHI range of 39-71 days whereas fodder PHIs ranged 66-123 days.

Samples of field corn forage and fodder were analyzed for dicamba and 5-OH dicamba using a GC/ECD method (Sandoz Method AM-0691B-0593-3) with a limit of detection of 0.01 ppm. The adequacy of the method for data collection was validated by separately fortifying control samples with dicamba and 5-OH dicamba at 0.01, 0.10, 0.50, and 1.0 ppm for forage and at 0.5 and 1.0 ppm for fodder. Method recoveries were within the acceptable range. The HED review did not capture information pertaining to sample storage intervals. However, there are adequate storage stability data which indicate that dicamba and 5-OH dicamba residues are stable in/on corn matrices under frozen storage conditions for up to 3 and 2 years, respectively.

The results indicate that the total residues (dicamba + 5-OH dicamba) in/on all treated <u>forage</u> samples ranged from <0.01 to 2.27 ppm. Individual residues in forage were <0.01-0.31 ppm for dicamba and <0.01-1.97 ppm for 5-OH dicamba. In treated <u>fodder</u>, the total residues ranged from <0.01 to 2.45 ppm. Individual residues in fodder were <0.01-0.33 ppm for dicamba and <0.01-2.12 ppm for 5-OH dicamba. Analysis of Variance (ANOVA) statistical analysis was performed on the data collected from the 8 locations where the DMA, DGA, and Na dicamba salt formulations were used. The results indicate that the difference in the magnitude of the residues observed in forage and fodder was influenced by the difference in the trial locations and not by the difference in the dicamba salt formulations.

<u>Corn, pop, stover</u>

<u>Established tolerance(s)</u>: A tolerance of 3.0 ppm has been established for the combined residues of dicamba and its metabolite (5-OH dicamba) in/on pop corn stover [40 CFR §180.227 (a)(1)].

<u>Uses to be supported</u>: According to the Dicamba Master Use Profile (see Table 4), the DMA, Na, DGA, and K salts of dicamba will be supported on pop corn at a maximum single application rate of 0.5 lb ae/A and a maximum yearly rate of 0.75 lb ae/A.

<u>Conclusions</u>: There are no residue data on pop corn stover reflecting the maximum rate of 0.75 lb ae/A which is the maximum single/yearly application rate the registrants wish to support for pop corn. HED will allow the translation of available data from field corn stover to pop corn stover since the Dicamba Master Use Profile indicates that the application rate of the two crops is identical. However, any label revision for field corn should also be made for pop corn. Concurrently, any adjustment to the field corn stover tolerance should also be applied as necessary to the pop corn stover tolerance.

Millet (proso) forage, hay, and straw

Established tolerance: A tolerance of 0.5 ppm has been established for the combined residues of dicamba and its metabolite (5-OH dicamba) in/on proso millet straw [40 CFR §180.227 (a)(1)]. No tolerances have been established for proso millet forage and hay.

Uses to be supported: According to the Dicamba Master Use Profile (see Table 4), the DMA salt of dicamba will be supported on proso millet at a maximum single application rate of 0.125 lb ae/A and a maximum yearly rate of 0.125 lb ae/A.

Conclusions: The current RAC tolerance level of 0.5 ppm for millet straw was established through an IR-4 petition (PP#9E2166) based on residue data (MRID 00025330) reflecting application rates of 0.125 and 0.25 lb ae/A (1x and 2x). HED will allow the translation of available and requested data for wheat forage, hay, and straw to proso millet forage, hay, and straw since the Dicamba Master Use Profile indicates that the application rate of wheat is higher. Appropriate tolerance levels will be determined once all of the available studies have been reviewed.

Oat forage, hay, and straw

Established tolerance(s): Tolerances of 80.0 ppm, 20.0 ppm, and 0.5 ppm are currently established for the combined residues of dicamba and its metabolite (5-OH dicamba) in/on oat forage, hay, and straw, respectively [40 CFR §180.227 (a)(1)].

Uses to be supported: According to the Dicamba Master Use Profile (see Table 4), the DMA, Na, and DGA salts of dicamba will be supported on oats at a maximum single application rate of 0.125 lb ae/A and a maximum yearly rate of 1.0 lb ae/A.

Conclusions: There are no residue data on oat forage, hay, and straw reflecting the maximum rate of 1.0 lb ae/A which is the maximum single/yearly application rate the registrants wish to support for oats. For chronological perspective, it is noted that the tolerance for oat straw was initially established through PP#8F0666 based on limited data generated on spring-seeded oats from trials conducted in VA at application rates of 0.125 lb ae/A (0.125x). In conjunction with PP#s 6F4604 and 4F3041 (DP Barcode D249098, 10/13/98 W. Donovan), the tolerance for oat forage was revised to 80.0 ppm, and a tolerance for oat hay was established at 20 ppm based on residue data translated from wheat forage and hay; the cited petition reviews did not address the requirements for oat straw.

For the purpose of reregistration, HED will allow the translation of available and requested data for wheat forage, hay, and straw to oat forage, hay, and straw since the Dicamba Master Use Profile indicates that the application rate of the two crops is identical. Any label revision for wheat should also be made for oats. Concurrently, any adjustment to the wheat forage, hay, and straw tolerances should also be applied as necessary to the oat forage, hay, and straw tolerances.

Rye forage and straw

Established tolerance(s): No dicamba tolerances have been established for rye forage and straw.

Uses to be supported: According to the Dicamba Master Use Profile (see Table 4), the DMA salt of dicamba will be supported on rye at a maximum single application rate of 0.5 lb ae/A and a maximum yearly rate of 1.0 lb ae/A.

Conclusions: There are no available residue data on rye forage and straw. HED will allow the translation of available and requested data for wheat forage and straw to rye forage and straw since the Dicamba Master Use Profile indicates that the yearly application rate of the two crops is identical. Any label revision for wheat should also be made for rye. Concurrently, any adjustment to the wheat forage and straw tolerances should also be applied as necessary to the rye forage and straw tolerances that need to be established.

Sorghum forage and stover

MRID 43245203 (DP Barcodes D204488, D204809, and D209229; 7/14/97; L. Cheng)
MRID 44089306 (DP Barcodes D320550-320551; 12/05, C. Olinger)

Established tolerance(s): A tolerance of 3.0 ppm has been established for the combined residues of dicamba and its metabolite (5-OH dicamba) in/on sorghum forage and sorghum stover [40 CFR §180.227 (a)(1)].

Uses to be supported: According to the Dicamba Master Use Profile (see Table 4), all salts of dicamba will be supported on sorghum at a maximum single application rate of 0.2748 lb ae/A and a maximum yearly rate of 0.5 lb ae/A.

Conclusions: The registrant has submitted Craven replacement data depicting residues of dicamba and 5-OH dicamba in/on sorghum forage and fodder (stover). These data have been reviewed and deemed adequate to satisfy reregistration requirements pending label revisions and tolerance adjustments. The submitted data show that the maximum combined residues of dicamba and its 5-OH metabolite were 0.46 ppm (MRID 43245203) and 0.350 ppm (MRID 44089306) in/on sorghum forage samples harvested 20-72 days following a single postemergence application at 0.25 lb ae/A (0.5x the seasonal rate listed in the Dicamba Master Use Profile). The maximum combined residues were 8.22 ppm (MRID 43245203) and 4.29 ppm (MRID 44089306) in/on sorghum fodder samples collected at PHIs of 30-42 days following the last of two applications at 0.25 lb ae/A/application for a total rate of 0.5 lb ae/A (1x). These data suggest that the established tolerance for sorghum forage may be too high and the tolerance for fodder too low. Based on these data, HED is recommending tolerance levels of 0.5 ppm for sorghum forage and 10.0 ppm for sorghum stover concomitant with the following label revisions: (i) a 20-day PHI and a maximum single/seasonal rate of 0.25 lb ae/A for sorghum forage; and (ii) a 30-day PHI for sorghum fodder (stover) at a maximum seasonal rate of 0.5 lb ae/A. Following an examination of use directions for sorghum, HED will allow a lower use rate for forage since this RAC will be harvested prior to the second crop application.

Discussion of data: The submission for MRID 43245203 contain data depicting residues of dicamba and its 5-OH metabolite in/on sorghum forage and stover (fodder); this study also include data on sorghum silage which are not presented herein because silage is no longer considered a significant livestock feed item as per Table 1 of OPPTS 860.1000. A total of 40 field trials were conducted in KS(8), MO(8), NE(8), OK(8), and TX(8) using four salt formulations of dicamba: the Na, DGA, K, and DMA salts. Geographic representation of data is more than adequate when the trials conducted from this study along with those conducted from MRID 44089306 are considered. At each test site, one or two applications of each of the four dicamba salt formulations were made at 0.25 lb ae/A/application for total rates of 0.25 lb ae/A (~0.5x) and 0.5 lb ae/A (1x). Applications were made in 19.6-21.5 GPA using ground equipment. The 0.5x plots were treated when the plants were 15" tall using a broadcast application sprayed directly under the canopy (20-109 PTI). The 1x plots received an additional application of 0.25 lb ae/A when the crop was at the soft dough stage (30-42 PTI).

Sorghum forage and fodder samples were analyzed for residues of dicamba and 5-OH dicamba using a GC/ECD method (Method AM-0691B) with a limit of detection of 0.01 ppm for each analyte. The adequacy of the method for data collection was validated by fortifying untreated forage and fodder samples with dicamba and 5-OH dicamba at 0.01-0.1 ppm. Method recoveries were within the acceptable range. Samples were stored frozen at <-17 °C for 28-160 days (~1-5 months) prior to analysis. There are adequate storage stability data for corn matrices which can be translated to sorghum.

The results show that the combined residues of dicamba and its 5-OH metabolite ranged 0.029-0.46 ppm in/on sorghum forage samples harvested 20-54 days following a single postemergence application at 0.25 lb ae/A (0.5x). The combined residues ranged 0.132-8.22 ppm in/on sorghum fodder samples collected at PHIs of 30-42 days following the last of two applications at 0.25 lb ae/A/application for a total rate of 0.5 lb ae/A (1x).

MRID 44089306: A total of seven sorghum trials were conducted in Regions 2 (NC; 1 trial), 4 (LA; 1 trial), 5 (IL and KS; 2 trials); 6 (OK; 1 trial), 7 (NE; 1 trial), and 8 (TX; 1 trial) during the 1995 growing season. The DMA salt of dicamba was the test formulation used in all trials. At each field trial site, two separate plots were treated with either a single post directed spray application made under the crop canopy of 15-inch tall sorghum plants at a rate of 0.25 lb ae/A (0.5x) or two applications (one post directed application followed by a second broadcast application made at soft dough stage) at 0.25 lb ae/A/application, with a 44- to 65-day retreatment interval, for a total rate of 0.5 lb ae/A (1x). Applications were made in 10-36 gal/A of water using ground equipment. Forage samples were collected from 0.5x-treated sites at PHIs of 49-72-days. Fodder samples were collected from the 1x-treated sites at PHIs of 30-34 days.

Samples were analyzed for residues of dicamba and its 5-OH metabolite using GC/ECD method AM-0691B-0593-3 with a validated LOQ of 0.02 ppm for each analyte. The method is adequate for data collection based on acceptable concurrent method recovery data. Samples were stored frozen for 56-137 days (1.8-4.5 months) for forage and 43-191days (1.4-6.3 months) for fodder prior to residue analysis. There are adequate storage stability data for corn matrices which can be translated to sorghum.

The results show that the maximum combined residues of dicamba and its 5-OH metabolite were 0.350 ppm in/on sorghum forage harvested 49-72 days following a single post directed spray application at 0.25 lb ae/A (0.5x). The maximum combined residues were 4.29 ppm in/on sorghum fodder harvested 30-34 days following the last of two applications (one post directed followed by a second broadcast application made at soft dough stage) at 0.25 lb ae/A/application for a total rate of 0.50 lb ae/A (1.0x).

Wheat forage and hay

MRID 43274501 (DP Barcodes D220469, D220471, D220473, and D220430; 5/2/96; F. Griffith)
MRID 44891302 (DP Barcodes D320563; 11/24/05; C. Olinger)

Established tolerance(s): Tolerances of 80.0 ppm and 20.0 ppm are currently established for the combined residues of dicamba and its metabolite (5-OH dicamba) in/on wheat forage and hay, respectively [40 CFR §180.227 (a)(1)].

Uses to be supported: According to the Dicamba Master Use Profile (see Table 4), the DMA, Na, DGA, and IPA salts of dicamba will be supported on wheat at a maximum single application rate of 0.5 lb ae/A and a maximum yearly rate of 1.0 lb ae/A.

Conclusions: The registrant has submitted data (MRID 43274501) from seven field trials depicting residues of dicamba and 5-OH dicamba in/on wheat forage and hay. These data have been reviewed and deemed inadequate because of inadequate geographic representation of data. The registrant has committed (DP Barcodes D228694 and D239967, 6/25/98, S. Chun) to conduct additional wheat forage and hay field trials. This study has been submitted and reviewed (MRID 44891302) and is considered adequate.

The available data, indicate that the maximum combined residues of dicamba and 5-OH dicamba were 86 ppm in/on wheat forage samples harvested immediately (0-day PHI) following a single application of dicamba at 0.5 lb ai/A. In wheat hay, the maximum combined residues were 34 ppm from samples harvested 14 days following a single application of dicamba at 0.5 lb ai/A. These data indicate the existing tolerance for wheat forage should be increased to 90 ppm and the tolerance for wheat hay should be increased to 40 ppm.

Discussion of wheat forage and hay data: The submission for MRID 43274501 contain data depicting residues of dicamba and 5-OH dicamba in/on wheat forage and hay from seven trials conducted during the 1993 growing season. The locations of wheat trials from the subject study are as follows: Regions 5 (KS; 1 trial), 6 (TX; 1 trial), 7 (ND; 1 trial), 8 (CO and KS; 2 trials), 9 (MT; 1 trial), and 11 (WA; 1 trial). The initial HED review of this study (DP Barcodes D220430, ... 5/2/96, F. Griffith) concluded that geographic representation of data is inadequate. The registrant has subsequently committed to conduct additional wheat forage and hay field trials (DP Barcodes D228694 and D239967, 6/25/98, S. Chun).

Five of these trials were with winter wheat varieties, and two were with spring wheat varieties. Each trial location consisted of a control plot and six test plots for three different dicamba formulations (DMA, DGA, and Na salts) at two different application rates. Three treated test plots received one application at 0.125 lb ai/A in 9-31 gallons of water using ground equipment with wheat forage samples harvested at a 0-day PHI. The other three test plots received one application at 0.5 lb ai/A with wheat forage samples harvested at a 0-day PHI. Wheat hay samples from all test plots were cut 14 days later and allowed to field dry 3-7 days before collection/harvest as wheat hay. Samples were analyzed for dicamba and 5-OH dicamba using a GC/ECD method (Method AM-0691B-0593-3) with an LOQ of 0.01 ppm. Recovery data for wheat forage and hay were acceptable to support the method as suitable to gather the magnitude of the residue data. Samples were stored frozen for an unspecified interval prior to residue analysis. The HED review concluded that there are adequate storage stability data on wheat forage and hay which support sample storage conditions and intervals.

The results show that all field trials from the 0.125 lb DMA dicamba application to wheat forage had detectable residues at 0-day PHI ranging from 6.7 to 16 ppm (2 trials). Maximum residues were 14 ppm when the DGA dicamba was applied, and 12 ppm from the application of the Na salt. Likewise, all wheat hay samples had detectable total dicamba results. Total residues of dicamba on 14-day PHI wheat hay ranged from 0.62 ppm to 4.9 ppm from application of DMA dicamba. Maximum residues were 4.6 ppm from the application of DGA dicamba, and 4.8 ppm from the application of the Na salt.

BASF Corporation has submitted wheat forage and hay field trial data for dicamba (MRID 44891302). Fourteen trials were conducted in the United States encompassing Zones 2, 5, 7, and 8 during the 1998 harvest. At each test location, a single application of dicamba was made at an application rate of 0.5 lb a.i./A. An adjuvant added to the spray mixture for all applications. Wheat forage was harvested the day of application and hay was cut 14 days later, followed by drying for 2 to 10 days.

Method AM-0691B-0297-4 was used to analyze for residues of dicamba and 5-hydroxydicamba, and has been shown to be adequate as a data collection method. Residues of dicamba have been shown to be stable for the duration of storage that occurred during the conduct of this study, 11 months. Residues of dicamba in wheat forage harvested the day of application ranged from 22.0 ppm to 85.48 ppm. Residues of 5-OH-dicamba were non-detectable (at a limit of quantitation of 0.5 ppm) in most forage samples; the highest detectable value was 1.56 ppm. Residues of dicamba in wheat hay ranged from 0.62 to 14.2 ppm. while the residues of 5-OH-dicamba were much higher than forage, ranging from 3.22 to 20.32 ppm

<u>Wheat straw</u>

MRID 44089305 (DP Barcode D228703, 7/16/98, S. Chun)

<u>Established tolerance:</u> A tolerance of 30.0 ppm has been established for the combined residues of dicamba and its metabolite (5-OH dicamba) in/on wheat straw [40 CFR §180.227 (a)(1)].

Uses to be supported: According to the Dicamba Master Use Profile (see Table 4), the DMA, Na, DGA, and IPA salts of dicamba will be supported on wheat at a maximum single application rate of 0.5 lb ae/A and a maximum yearly rate of 1.0 lb ae/A.

Conclusions: There are Craven replacement data (MRID 44089305) depicting residues of dicamba and 5-OH dicamba in/on wheat straw. These data, however, do not support the maximum seasonal rate of 1.0 lb ae/A that is listed in the Dicamba Master Use Profile because the wheat trials were conducted at application rates of 0.25 or 0.5 lb ae/A. The combined residues of dicamba and 5-OH dicamba ranged from 0.011 to 0.97 ppm in/on samples of wheat straw harvested 63-125 days following one spring broadcast application of representative dicamba salt formulations at 0.25 lb ae/A (0.25x). The combined residues ranged from 0.13 to 26 ppm in/on straw samples harvested 6-12 days following the last of two treatments for a total of 0.5 lb ae/A (0.5x).

For the purpose of reregistration, the registrants are required to submit additional data on wheat straw reflecting a maximum seasonal rate of 1.0 lb ae/A. Alternatively, the registrants may rely on the available data provided they are willing to revise product labels for consistency with the reviewed data. If the registrants elect to choose the latter option, then they will be required to revise product labels to specify a maximum seasonal rate of 0.5 lb ae/A and a 7-day PHI for wheat straw. The existing tolerance of 30 ppm for wheat straw will be considered adequate *if* the registrants elect to revise product labels.

Discussion of data: The submission for MRID 44089305 report data depicting residues of dicamba and 5-OH dicamba in/on wheat straw. A total of 20 field trials were conducted during the 1995 growing season in16 states: CO(2), ID, IL, KS(2), MN, MO, MS, MT(2), NE, NM, NC, ND, OH, OK(2), TX, and WY. These states cover EPA regions II (1), IV (1), V(5), VI (1), VII (5), VIII (6), and XI (1). Geographic representation of data is adequate since the number and location of wheat trials is in accordance with Tables 1 and 5 of GLN 860.1500. The wheat field trials were conducted using the following salt formulations of dicamba: DMA, DGA, and Na.

Two treatment patterns, designated as A and B, were employed in this study. Treatment A consisted of a spring broadcast application at 0.25 lb ae/A (0.25x) made to the crop immediately prior to first joint (POPO1). Treatment B consisted of Treatment A plus a preharvest broadcast application at 0.25 lb ae/A, made 7 days before harvest (POPO2) for a total of 0.5 lb ae/A (0.5x). The DMA salt formulation of dicamba was applied in 10 trial locations. Side-by-side trials with the DMA, DGA, and Na salt formulations of dicamba were conducted at four trial locations to compare the residues found from use of the different salt formulations. Samples were analyzed for dicamba and 5-OH dicamba using a GC/ECD method (Sandoz Method AM-0691B-0593-3) with a limit of detection of 0.01 ppm. The adequacy of the method for data collection was validated by fortifying straw control samples with dicamba and 5-OH dicamba at 0.02 and 0.10 ppm. Method recoveries were within the acceptable range. However, the HED review noted that the method was not validated over an acceptable range since residue levels in wheat straw were found well above the ranges of the method validation. The HED review, thus, requested additional method validation at a spike level of up to 30 ppm for wheat straw. Wheat straw samples were stored frozen for 51-220 days (~2-7 months) prior to residue analysis. There are adequate storage stability data available for field corn matrices which may be translated to wheat straw.

The results indicate that the total residues (dicamba + 5-OH dicamba) in/on all treated straw samples ranged 0.011-0.97 ppm for Treatment A (0.25x) and 0.13-26 ppm for Treatment B (0.5x). Analysis of Variance (ANOVA) statistical analysis was performed on the data collected from the four locations where the DMA, DGA, and Na dicamba salt formulations were used. The results indicate that the difference in the magnitude of the residues observed in straw was influenced by the difference in the trial locations and not by the differences in the dicamba salt formulations.

Grass, Forage, Fodder, and Hay, Group 17

Pasture and rangeland grasses

MRID 43370701 (DP Barcode D207649, 3/11/96, L Cheng)
(DP Barcodes D220469, D220471, D220473, and D220430; 5/2/96; F. Griffith)
(DP Barcodes D228694 and D239967, 6/25/98, S. Chun)

Established tolerance(s): Tolerances for Crop Group 17 (grass, forage, fodder, and hay group) are currently established for the combined residues of dicamba and its metabolite (5-OH dicamba) in/on grass forage at 125.0 ppm and grass hay at 200.0 ppm [40 CFR §180.227 (a)(1)].

Uses to be supported: The Dicamba Master Use Profile (see Table 4) lists separate entries on: (i) hay; (ii) pastures; (iii) rangeland; and (iv) Sudangrass. On hay, the DMA, Na, and DGA salts of dicamba will be supported at a maximum single and yearly application rate of 2.0 lb ae/A based on labels for EPA Reg. Nos. 51036-289 and 7969-131. On pastures and rangeland, the DMA, Na, and DGA salts of dicamba will be supported at a maximum single and yearly application rate of 2.0 lb ae/A. There is an endnote in Table 4 which specifies that the label for EPA Reg. No. 100-884 lists 7.7 lb ae/A as the maximum rate for spot treatment of pastures and rangelands. The 2.0 lb ae/A is what the registrant stated at the SMART Meeting as the rate they intended to support. On Sudangrass, the DMA salt of dicamba will be supported at a maximum single rate of 0.5 lb ae/A for hay and a maximum yearly rate of 1.0 lb ae/A.

Conclusions: An acceptable study (MRID 43370701) depicting residues of dicamba and 5-OH dicamba is available and may be used to satisfy reregistration requirements pending tolerance adjustments and label amendments. This study was first reviewed by HED (DP Barcode 207649, 3/11/96, L Cheng) as a response to the requirements of the Dicamba (SRR) Registration Standard dated 6/30/89. The study was re-evaluated and addressed in conjunction with PP#6F4604: (i) DP Barcodes D220469, D220471, D220473, and D220430; 5/2/96; F. Griffith; and (ii) DP Barcodes D228694 and D239967, 6/25/98, S. Chun. The currently established tolerance levels of 125.0 ppm and 200.0 ppm for grass forage and hay, respectively, were established in conjunction with PP#6F4604 based on residue data reflecting a maximum seasonal application rate of 1.0 lb ae/A.

According to the Dicamba Master Use Profile, the registrants now wish to support a maximum single/yearly application rate of 2.0 lb ae/A for grasses grown in pastures and rangeland. For the purpose of generating this Chapter, the available grass forage and hay data were re-evaluated with the information that a maximum seasonal rate of 2.0 lb ae/A will be supported at a 0-day PHI/PGI for forage and a 7-day PHI for hay. The Agency currently requires zero-day crop field residue data for grasses cut for forage (unless its is not feasible, e.g., preplant/preemergence uses) but allow a reasonable interval before cutting for hay (Table I of OPPTS 860.1000). A 7-day PHI for grass hay is the interval that the registrants previously proposed in PP#6F4604.

The available data indicate that the combined residues of dicamba and 5-OH dicamba ranged 66-358 ppm in/on grass forage samples harvested immediately (0-day) following a single application of representative formulations of dicamba (DMA, DGA, or Na salts) at 2.0 lb ae/A (1x). The combined residues ranged 25-201 ppm in/on grass hay samples harvested 7 days following a single application of representative formulations at 2.0 lb ae/A (1x). Based on these data, HED is reassessing the grass forage tolerance at 400 ppm and the grass hay tolerance at 250 ppm.

Concomitant with these tolerance reassessment, HED is requesting RD to verify that all dicamba labels specify a 0-day PHI/PGI for grass forage and a 7-day PHI for grass hay when applied at a maximum of 2.0 lb ae/A. In addition, HED is recommending the removal of the spot treatment use on pastures and rangeland at 7.7 lb ae/A (from EPA Reg. No. 100-884) because there are no available data supporting this use rate; alternatively, the registrants may submit data to support this application rate.

Discussion of data: The submission for MRID 43370701 contain data depicting residues of dicamba and 5-OH dicamba in/on grass forage and hay. A total of 295 tests were conducted in FL(15), GA(35), IN(15), KS(15), TN(15), MI(15), NE(15), OK-1(35), OK-2(15), OR(35), MO(35), TX(15), and WI(35) using three formulations: the DMA, DGA, and Na salts of dicamba. Geographic representation of residue data is adequate with regard to the number of field trials. One application of the DMA salt was made at 0.5, 1.0, or 2.0 lb ae/A in separate tests at each test site. For the DGA and Na salts, one application was made at 0.5 or 2.0 lb ae/A in separate tests at each test site; however, samples were collected only from WI, MO, OR, GA, and OK-1 test sites. Applications were made in 7-23 GPA of water using ground equipment to actively growing grasses. Forage and hay samples were collected at 0, 7, 14, 28, and 56-day post treatment intervals (PTI). Hay samples were allowed to field dry for 2-3 days prior to collection. One to two controls samples were collected from the 7,14, 28, and 56-day PTI plots.

Samples were stored at <-1 °C for 72 to 402 days prior to analysis. This storage interval is supported by adequate storage stability data. Samples were analyzed for residues of dicamba and its hydroxy metabolite using GC/ECD Method AM-0691B which was deemed adequate for data collection based on acceptable concurrent method recoveries.

The results show that the combined residues of dicamba and 5-OH dicamba ranged 66-358 ppm in/on grass forage samples harvested immediately (0-day) following a single application of representative formulations of dicamba (DMA, DGA, or Na salts) at 2.0 lb ae/A (1x). The combined residues ranged 25-201 ppm in/on grass hay samples harvested 7 days following a single application of representative formulations at 2.0 lb ae/A (1x). Based on the results, it was concluded that dicamba residues are not dependent on which formulation is used, but may depend on the location where used.

Miscellaneous Commodities

Asparagus

MRIDs 43245206 and 43425803 (DP Barcodes D204488, D204809, and D209229; 7/14/97; L. Cheng)

Established tolerance(s): A tolerance of 4.0 ppm has been established for the combined residues of dicamba and its DCSA metabolite in/on asparagus [40 CFR §180.227 (a)(2)].

Uses to be supported: According to the Dicamba Master Use Profile (see Table 4), the DMA, Na, and DGA salts of dicamba will be supported on asparagus at a maximum single application rate of 0.5 lb ae/A and a maximum yearly rate of 0.5 lb ae/A.

Conclusions: The registrant has submitted adequate data depicting residues of dicamba and its DCSA metabolite in/on asparagus. These data indicate that the combined residues of dicamba and its DCSA metabolite ranged 0.28-3.29 ppm in/on asparagus (n=48 samples) harvested 24 hours following a single application of representative dicamba salt formulations at 0.5 lb ae/A (1x the maximum rate listed in the Dicamba Master Use Profile). These data support the currently established tolerance of 4.0 ppm on asparagus pending verification by RD that the label PHI for asparagus is 24 hours or 1 day.

Discussion of data: The submissions for MRIDs 43245206 and 43425803 contain data depicting residues of dicamba, 5-OH dicamba, and DCSA in/on asparagus. A total of 24 asparagus field trials were conducted in CA(3) and WA(3) in 1993 and in CA(6), MI(6), and WA(6) in 1994. The number and location of asparagus trials are adequate with respect to geographic representation of data. For the tests conducted in 1994, the six trials in each state represent two test locations (1 and 2) with three tests at each site. At each test site, the following three dicamba salt formulations were used: Na, DGA, and DMA. At each test site, one broadcast application of each of the three dicamba formulations was made at 0.5 lb ae/A (1x) in 20-50 GPA of water using ground equipment. Asparagus spears were harvested 24 hours after application.

Samples were analyzed for dicamba and DCSA using GC/ECD method AM-0766A. Additional samples were analyzed for 5-OH dicamba using method AM-0691B. These methods are adequate for data collection based on acceptable concurrent method recoveries. Samples were stored frozen at <-12 °C for 12-95 days prior to analysis. Adequate storage stability data are available which indicate that residues of dicamba and DCSA are stable in/on asparagus for up to 104 days of frozen (<-12 °C) storage, and that residues of 5-OH dicamba are also stable for up to 119 days of frozen (<-12 °C) storage.

The results show that the maximum combined residues of dicamba and DCSA were 1.1 ppm in/on 36 asparagus samples from CA and WA harvested 24 hours following a single application at 0.5 lb ae/A of the Na salt, DGA salt, or the DMA salt of dicamba. The maximum combined residues of dicamba and DCSA were 3.29 ppm in/on 12 asparagus samples grown in MI harvested 24 hours following a single application at 0.5 lb ae/A of the dicamba Na, DGA, or DMA salt formulation. The field trial data indicate that the residue levels are not dependent on the salt formulation used.

Aspirated grain fractions

MRID 43245205 (Sorghum) (DP Barcodes D204488, D204809, and D209229; 7/14/97, L. Cheng)
MRID 43814102 (Soybean) (DP Barcodes D223283, ..., 7/29/96; S. Knizner, W. Dykstra, and C. Lewis)
MRID 44089305 (Wheat) (DP Barcode D228703, 7/16/98, S. Chun)

Established tolerance(s): A tolerance of 5100 ppm has been established for the combined residues of dicamba and its metabolites (5-OH dicamba and DCSA) in/on aspirated grain fractions [40 CFR §180.227 (a)(3)].

Uses to be supported: Refer to "Legume Vegetables (Crop Group 6)" section for supported uses on soybean seed and "Cereal Grains (Crop Group 15)" section for supported uses on field corn, sorghum, and wheat.

Conclusions: There are adequate residue data on the aspirated grain fractions (also known as grain dusts) of sorghum, soybean, and wheat. [Although samples collected from the sorghum and wheat studies were only analyzed for dicamba and 5-OH dicamba, HED would not ask registrants to repeat these studies because samples from the soybean study, which produced the highest residues, were analyzed for dicamba, 5-OH dicamba, and DCSA.] Summaries of the submitted grain dust data are presented below. The highest processing factor found was 670x, for dicamba in soybean seed aspirated grain fractions. The average residues found in the field trial application schedule was 1.36 ppm. Multiplying 670 by 1.36 yields 941 ppm, so the rounded value for the reassessed tolerance would be 1000 ppm.

Sorghum aspirated grain fractions: Two trials were conducted in Peru (1) and Dodge City (1), KS depicting residues of dicamba and 5-OH dicamba in/on the aspirated grain fractions of sorghum. Applications were made at a total of 0.5 lb ae/A (1x the maximum yearly rate listed in the Dicamba Master Use Profile) and 1.5 lb ae/A (3x) at both sites. Grain samples were harvested and analyzed by Sandoz Agro, Inc. (Des Plaines, IL) as pre-qualifier samples. The 3x-trial from Dodge City bore the highest residues in grain samples, therefore, only treated samples from this trial were processed for grain dust generation. Grain dust was generated in a steel bucket elevator using a process that was designed to simulate a commercial elevator operation. Upon generation, the grain dust samples were sent to the analytical facility of Sandoz where they were held frozen at <-17 °C for up to 2 months prior to analysis. The treated RAC sample was held frozen for 4 months prior to analysis. One treated grain sample and one of each >2030, >1180, >850, >425, and <425 μm treated grain dust samples were analyzed. Residues of dicamba and 5-OH dicamba were determined using the GC/ECD method AM-0691B which is adequate for data collection. Following treatment at a total of 1.5 lb ae/A, the maximum combined residues of dicamba and 5-OH dicamba were 6.9 ppm in/on sorghum grain (RAC) and 27.1 ppm in/on the aspirated grain fractions of sorghum. Individual ranges of residues in/on treated sorghum grain dusts were 10.0-17.6 ppm and 3.2-9.5 ppm for dicamba and 5-OH dicamba, respectively.

Soybean aspirated grain fractions: One trial was conducted in IL depicting residues of dicamba, DCSA, and 5-OH dicamba in/on the aspirated grain fractions of soybeans. In this trial, soybean seeds were harvested 5 days following a single preharvest broadcast application of the 4 lb/gal soluble concentrate DMA formulation of dicamba at 10 lb ae/A (5x the maximum rate listed in the Dicamba Master Use Profile). Samples were harvested using a combine, and the harvested samples were transported in gravity flow wagons to the machine shed for bagging. Samples were frozen within 3 hours of harvest and shipped frozen to the processing facility, Texas A &M Food Protein Research and Development Center (Bryan, TX) 26 days after harvest. Adequate descriptions of procedures used for the generation of soybean grain dusts were included in the study. It is, however, noted that grain dust was separated into various fractions by sieving, and that the sieved fractions were then recombined before residue analysis. Samples were analyzed for residues of dicamba, 5-OH dicamba, and DCSA using GC Method No. AM-0941-1094-0 with an LOQ of 0.01 ppm for each soybean matrix. In this method, residues of dicamba and DCSA were quantitated by GC with a Ni ECD, while residues of 5-OH dicamba were quantitated separately by GC/ECD. The data-collection method used is adequate based on acceptable recoveries from method validations. All samples were stored frozen at the analytical laboratory prior to analysis. Total storage interval, between harvest and analysis, were 146-170 days (5-6 months) for grain dusts.

The results of the study indicate that the average residues of dicamba, 5-OH dicamba, and DCSA in/on two treated soybean seed (RAC) samples were 0.543 ppm, <0.01 ppm, and 0.014 ppm, respectively. In treated soybean aspirated grain fractions, for which >50% of the fractions were <425 µm in size, the average residues were: 365 ppm for dicamba, 2.8 ppm for 5-OH dicamba, and 3.0 ppm for DCSA.

Wheat aspirated grain fractions: For the generation of wheat grain dust, 30-lb grain samples were collected from the wheat field trials and batched together. The grain samples were dried at 110-150 °F until the moisture content was 10-13%. The grain samples were then placed in a dust generation room on a drag conveyor and moved for 120 minutes. As the sample was moved in the system. aspiration was used to remove the grain dust. The resulting dust was classified by size using sieves. The whole grain, representing the RAC before the generation of grain dusts, bore a combined residue (dicamba + 5-OH dicamba) of 0.44 ppm. The grain dust samples had combined residues of 4.8 ppm (>425 µm to <2030 µm) and 4.7 ppm (<425 µm).

Cotton, undelinted seed and gin byproducts

MRID 43814001 (DP Barcodes D220469, D220471, D220473, and D220430; 5/2/96; F. Griffith)
MRID 45196801 (DP Barcode D320570; 11/24/05; C. Olinger)

Established tolerance(s): A tolerance of 5.0 ppm has been established for the combined residues of dicamba and its metabolite (5-OH dicamba) in/on undelinted cottonseed [40 CFR §180.227 (a)(1)]. No tolerance is established for cotton gin byproducts.

Uses to be supported: According to the Dicamba Master Use Profile (see Table 4), the DMA, and DGA salts of dicamba will be supported on field corn at a maximum single application rate of 0.25 lb ae/A and a maximum yearly rate of 2.0 lb ae/A.

Conclusions: Field trial data indicate that the established tolerance in/on cottonseed can be reduced to 0.2 ppm. Additional information on weather during the conduct of the study and harvesting technics is needed before a tolerance can be established in/on cotton gin by-products.

Discussion of the Data: In MRID 43814001, 12 field trials were conducted in 1994 as follows: one from Region 2 [Georgia], 8 from Region 4 [Louisiana (3), Mississippi (2), Tennessee, and Arkansas (2)], two from Region 6 [Texas], and one from Region 8 [Texas]. The dicamba sodium salt formulation was applied once at the 0.5 lb ai/acre rate in 10-20 gallons of water using ground equipment 14 days prior to planting cotton. Cotton was harvested at maturity by hand, ginned with the lint discarded, and the cottonseed and gin by-products (consisting of burrs, stems, and leaves) were collected for analysis. The maximum residue detected in cottonseed from the proposed new use is 0.05 ppm of the 5-OH metabolite in only one field trial. Several control cotton gin by-product samples contained dicamba or 5-OH dicamba equivalents in the 0.04-0.06 ppm range. which was comparable to the levels found in the treated samples.

BASF Corporation has submitted field trial data (MRID 451968010 for the herbicide dicamba on cotton gin by-products. Six trials were conducted in the United States encompassing Zones 4 (2 trials), 8 (3 trials) and 10 (1 trial) during the 1998-99 growing season. At each test location, dicamba was applied at a rate of 2 lb ai/A to fallow ground after the previous crop was harvested. An adjuvant was added to the spray mixture for all applications. The cotton gin by-products were harvested the following year.

Method AM-0691B-0297-4 was used to analyze for residues of dicamba and its metabolite 5-hydroxydicamba (5-OH-dicamba), and has been shown to be adequate as a data collection method. Residues of dicamba have been shown to be stable for the duration of storage that occurred during the conduct of this study, 2.5 months. Residues of dicamba and 5-OH-dicamba were less than the limit of quantitation (0.05 ppm) in all trials, with the exception of one of the Texas trials, where the combined residues were 0.76 ppm. Additional information regarding weather conditions and harvesting techniques are required before this study can be considered acceptable.

Sugarcane

MRID 44089302 (DP Barcodes D320550-320551; 12/05; C. Olinger)

Established tolerance(s): Tolerances of 0.1 ppm are currently established for the combined residues of dicamba and its metabolite (5-OH dicamba) in/on sugarcane, sugarcane forage, sugarcane fodder [40 CFR §180.227 (a)(1)]. The Agency no longer considers sugarcane forage and fodder to be significant livestock feed items, and these items have been deleted from Table 1 of OPPTS 860.1000. Therefore, HED is recommending the revocation of the tolerances for sugarcane forage and fodder.

Uses to be supported: According to the Dicamba Master Use Profile (see Table 4), the DMA, Na, and DGA salts of dicamba will be supported on sugarcane at a maximum single application rate of 2.8 lb ae/A and a maximum yearly rate of 2.8 lb ae/A.

Conclusions: There are Craven replacement data (MRID 44089302) depicting residues of dicamba and 5-OH dicamba in/on sugarcane. These data, however, do not support the maximum seasonal single/yearly rate of 2.8 lb ae/A that is listed in the Dicamba Master Use Profile because the sugarcane trials were conducted at an application rate of 2.0 lb ae/A (~0.7x). The submitted data indicate that the maximum combined residues of dicamba and its 5-hydroxy metabolite were 0.202 ppm, 0.186 ppm, and 0.054 ppm in/on sugarcane harvested 87-173 days following a single layby application of the respective DMA, DGA, Na salt formulations of dicamba to sugarcane crop at 2.0 lb ae/A. The maximum combined HAFT level was 0.183 ppm obtained from samples treated with the DGA salt.

For the purpose of reregistration, the registrants are required to submit additional data on sugarcane reflecting a maximum single/yearly rate of 2.8 lb ae/A. Alternatively, the registrants may rely on the available data provided they are willing to revise product labels for consistency with the reviewed data. If the registrants elect to choose the latter option, then they will be required to revise product labels to specify a maximum seasonal rate of 2.0 lb ae/A and an 87-day PHI for sugarcane. The existing tolerance of 0.1 ppm for sugarcane is inadequate and HED is recommending that it be reassessed at 0.3 ppm *if* the registrants elect to revise product labels as detailed above.

Discussion of data: The submission for MRID 44089302 depict residues of dicamba and its metabolite (5-OH dicamba) in/on sugarcane. A total of eight sugarcane trials were conducted in Regions 3 (FL; 3 trials), 4 (LA; 3 trials), 6 (TX; 1 trial), and 13 (HI; 1 trial) during the 1995 growing season. The number and locations of field trials are adequate and in accordance with OPPTS Guideline 860.1500. At three test locations (FL, HI, and LA), the DMA, DGA, Na salt formulations of dicamba were applied side-by-side to separate plots of sugarcane at layby at a rate of 2.0 lb ae/A (~0.7x the maximum yearly rate listed in the Dicamba Master Use Profile). At the remaining five test locations (FL; 2 trials, LA; 2 trials, and TX; 1 trial), a single application of the DMA salt formulation was also made at layby at the same rate. Applications were made in 15-30 gal/A of water using ground equipment. Sugarcane was harvested 87-173 days posttreatment.

Samples were analyzed for residues of dicamba and its hydroxy metabolite using GC/ECD method AM-0691B-0593-3. The validated LOQ is 0.02 ppm for dicamba and 5-OH dicamba. The LOD is 0.01 ppm. The method is adequate for data collection based on acceptable concurrent method recovery data. The maximum storage intervals of sugarcane samples from harvest to analysis were 140 days (4.6 months). No storage stability data are available for sugarcane. HED will translate the available storage stability data for corn forage and fodder to sugarcane. These data (MRID 43866601; D228703, S. Chun, 7/16/98) indicate that residues of dicamba and 5-OH dicamba are stable in/on all corn RACs (forage, silage, grain, and fodder) stored frozen for up to 3 and 2 years, respectively.

The results show that the maximum combined residues of dicamba and its 5-hydroxy metabolite were 0.202 ppm, 0.186 ppm, and 0.054 ppm in/on sugarcane harvested 87-173 days following a single layby application of the respective DMA, DGA, Na salt formulations of dicamba at 2.0 lb ae/A. The maximum combined HAFT level was 0.183 ppm obtained from samples treated with the DGA salt.

860.1520 Processed Food and Feed

Barley

Established tolerance(s): No tolerance has been established for the combined residues of dicamba and its metabolite (5-OH dicamba) in/on any barley processed commodities.

Conclusions: There are no available barley processing data with dicamba. Consistent with the recommendation of the Dicamba SRR, HED will allow translation of the submitted wheat processing data to barley. The most recent acceptable wheat processing study (MRID 42675901) indicates that the combined residues of dicamba and 5-OH dicamba did not concentrate in any of the wheat processed fractions. Thus, tolerances in the barley processed fractions (pearled barley, flour, and bran) are not necessary.

Corn

MRID 41187301 (DP Barcode D320555; 11/24/05; C. Olinger)

Established tolerance(s): No tolerance has been established for the combined residues of dicamba and its metabolite (5-OH dicamba) in/on any corn processed commodities.

Conclusions: A corn processing study (MRID 41187301) recently reviewed indicated that residues of dicamba and 5-hydroxydicamba do not concentrate in corn processed products. Tolerances for the processed commodities of corn are not needed. No additional corn processing data are required.

Discussion of the Data: The potassium salt of dicamba acid was applied to corn at either 2 or 10 lb a.i./, and harvested 7 days after final treatment. Only the corn grain from the higher treatment rate plot were processed via wet and dry milling processes into hulls, flour, grits, corn meal, soapstock, crude oil, refined oil gluten, and starch. An adequate analytical method was used to analyze the raw and processed commodities for residues of dicamba and 5-hydroxy dicamba (5-OH-dicamba). Samples were analyzed within intervals of demonstrated stability for soybean and soybean processed products. Residues of dicamba per se did not concentrate in any processed commodity, with reduction factors ranging from 0.31 to less than 0.03. Processing factors could not be determined for 5-OH-dicamba because residues were non-detectable in the raw and processed commodities.

Cottonseed

Established tolerance(s): A tolerance of 5.0 ppm has been established for the combined residues of dicamba and its metabolite (5-OH dicamba) in/on cotton meal [40 CFR §180.227 (a)(1)].

Conclusions: An acceptable cottonseed processing study is available (PP#1G2502, 7/28/81, A. Rathman). Residues were generally reduced with the exception of cottonseed meal, which concentrated 1.9x. The reassessed tolerance level for cottonseed is greater than the highest average field trial level (HAFT) multiplied by the concentration factor in meal, so a separate tolerance for meal is not needed.

Millet

Established tolerance(s): No tolerance has been established for the combined residues of dicamba and its metabolite (5-OH dicamba) in/on any millet processed commodities.

Conclusions: According to Table 1 of OPPTS 860.1000, the only processed commodity associated with millet is flour. Endnote 44 of Table 1 specifies that millet flour is not produced significantly in the U.S. for human consumption, and residue data are not needed at this time.

Oat

Established tolerance(s): No tolerance has been established for the combined residues of dicamba and its metabolite (5-OH dicamba) in/on any oat processed commodities.

Conclusions: There are no available oat processing data with dicamba. Consistent with the recommendation of the Dicamba SRR, HED will allow translation of the submitted wheat processing data to oats. The most recent acceptable wheat processing study (MRID 42675901) indicates that the combined residues of dicamba and 5-OH dicamba did not concentrate in any of the wheat processed fractions. Thus, tolerances in the oat processed fractions (flour and groats/rolled oats) are not necessary.

Sorghum

Established tolerance(s): No tolerance has been established for the combined residues of dicamba and its metabolite (5-OH dicamba) in/on any sorghum processed commodities.

Conclusions: The Dicamba SRR (6/89) required a sorghum processing study depicting the combined residues of dicamba and its hydroxy metabolite in milled products (flour and starch) and grain dust from sorghum grain bearing measurable, weathered residues. In response, the registrant submitted a protocol (S. Knizner, 6/11/93) and a rebuttal to the review of the protocol (R. Perfetti, 10/20/93). The Agency concluded that residue data are not required for sorghum flour or starch, but data are required for the aspirated grain fractions of sorghum. Based on this previous HED determination, a sorghum processing study is not required for reregistration. Data on sorghum grain dusts have been submitted and reviewed; these data are presented under "Aspirated grain fractions" section of Miscellaneous Commodities.

Soybean

MRID 43814102 (DP Barcodes D223283, ... 7/29/96; S. Knizner, W. Dykstra, and C. Lewis)

Established tolerance(s): A tolerance of 13 ppm has been established for the combined residues of dicamba and its two metabolites (5-OH dicamba and DCSA) in soybean hulls [40 CFR §180.227 (a)(3)].

Conclusions: An acceptable soybean processing study with dicamba, submitted as an alternate to previous data generated by Craven Laboratories, is available. The results indicate that residues of dicamba concentrated by a factor of 3.8x in soybean hulls but did not concentrate in any of the other soybean processed fractions (meal, crude oil and refined oil). The HAFT combined residues from the two soybean field studies, reflecting both the preplant and preharvest uses at 2.5 lb ae/A (1.25x), are: 3.6 ppm (MRID 43814101) and 7.44 ppm (MRID 44089307). When the HAFT combined residue level (7.44 ppm) is multiplied by the observed concentration factor for soybean hulls (3.8x), the resulting level is 28.272 ppm which suggests that the existing tolerance of 13.0 ppm for soybean hulls needs increasing. For the purpose of tolerance reassessment, HED recommends that the tolerance for soybean hulls be increased from 13.0 ppm to 30.0 ppm. Tolerances in the soybean processed fractions of meal and refined oil are not necessary.

Discussion of data: In the subject study (MRID 43814102), soybeans grown in IL were harvested five days following a single preharvest broadcast application of a formulation containing the DMA salt of dicamba at 10 lb ae/A (5x). Soybean seeds were harvested, and the collected samples were frozen and shipped to Texas A & M Food Protein Research and Development for processing according to simulated commercial procedures. RAC samples were processed into crude and refined oil, meal, hulls and soapstock; aspirated grain fractions were also collected.

The treated soybean seed (RAC) bore average residues of 0.543 ppm for dicamba, <0.01 ppm for 5-OH dicamba, and 0.014 ppm for DCSA. Following processing, the average residues of the parent and its metabolites in the processed fractions were: (i) meal (0.190 ppm dicamba + <0.01 ppm 5-OH dicamba + <0.01 ppm DCSA); (ii) hulls (2.088 ppm dicamba + <0.01 ppm 5-OH dicamba + <0.01 ppm DCSA); (iii) crude oil (<0.01 ppm dicamba + <0.01 ppm 5-OH dicamba + <0.01 ppm DCSA); and (iv) refined oil (<0.01 ppm dicamba + <0.01 ppm 5-OH dicamba +

<0.01 ppm DCSA). Samples were analyzed by a GC/ECD method (Method AM-0941-1094-0). The data-collection method is adequate based on acceptable concurrent method recoveries. Samples were stored frozen before residue analysis. Total storage intervals between harvest and analysis were approximately 6 months for seed, 5 months for meal, 5-6 months for hulls, and 4 months for refined oil. These storage intervals are supported by adequate storage stability data. The study also included data on the aspirated grain fractions of soybeans. The results of this portion of study are presented under "Aspirated Grain Fractions" section of Miscellaneous Commodities.

Sugarcane

MRID 43245204 (DP Barcodes D204488, D204809, and D209229; 7/14/97; L. Cheng)

Established tolerance(s): A tolerance of 2.0 ppm has been established for the combined residues of dicamba and its metabolite (5-OH dicamba) in sugarcane molasses [40 CFR §180.227 (a)(1)].

Conclusions: Pending submission of supporting storage stability data and adjustment of tolerance level for sugarcane molasses, an adequate sugarcane processing study is available. The study results show that the combined residues of dicamba and 5-OH dicamba were 0.054 ppm in/on the RAC (sugarcane) harvested 130 days following a single broadcast application of the DMA salt formulation of dicamba to sugarcane at layby at a rate of 5.0 lbs ae/A (~1.8x). Following processing of treated RAC samples, the combined residues were nondetectable (<0.01 ppm) in refined sugar but concentrated in bagasse (processing factor of 6.6x) and molasses (processing factor of 24.4x); bagasse has been deleted from Table 1 of OPPTS 860.1000 as a significant livestock feed item and is no longer regulated.

The initial HED review of the subject processing study previously reported that in PP#1F2569, the HAFT was 0.036 ppm (Accession # 070319, Belle Glade, FL, 3 lb ae/A and PHI of 158 days). A more recent sugarcane field study (MRID 44089302) reported a combined HAFT residue of 0.183 ppm from RAC samples harvested 87-173 days following a single layby application of the DGA salt formulations at 2.0 lb ae/A. When the maximum HAFT combined residue level (0.183 ppm) is multiplied by the observed concentration factor for molasses (24.4x), the resulting level is 4.465 ppm which is higher than the currently established tolerance of 2.0 ppm for sugarcane molasses. For the purpose of tolerance reassessment, HED recommends that the tolerance for sugarcane molasses be increased from 2.0 ppm to 5.0 ppm. A tolerance in refined sugar is not necessary.

Discussion of data: A sugarcane processing study (MRID 43245204) depicting magnitude of the residues of dicamba and 5-OH dicamba is available. To generate samples for processing, two trials were conducted in Opelousas (1) and Washington (1), LA. At each trial site, a single broadcast application of the DMA salt formulation of dicamba was applied at 5.0 lbs ae/A (~1.8x) to sugarcane at layby. Applications were made in 10 and 11.6 GPA. RAC samples from both sites were harvested and analyzed by Sandoz Agro, Inc. (Des Plaines, IL) as prequalifier samples. Residues in the RAC (130-day PTI) sample collected from the Washington, LA trial were higher, and this sample was the only one processed. The RAC sample was processed within 15 days of harvest following standard commercial practices into bagasse, molasses, and refined sugar by the Audubon Sugar Institute at Louisiana State University in Baton Rouge.

Samples were analyzed for residues of dicamba and its hydroxy metabolite using GC/ECD method AM-0691B-0593-3. The validated LOQ is 0.02 ppm for dicamba and 5-OH dicamba. The LOD is 0.01 ppm. The method is adequate for data collection based on acceptable concurrent method recovery data. The RAC and processed samples were stored frozen (<-1 °C) for up to 58 and 64 days, respectively, prior to analysis. The available storage stability data are adequate to support the storage interval and conditions for refined sugar. However, the HED review required supporting storage stability data for molasses before the study may be deemed acceptable.

The results show that the combined residues of dicamba and 5-OH dicamba were 0.054 ppm in/on the RAC (sugarcane) harvested 130 days following a single broadcast application of the DMA salt formulation of dicamba at 5.0 lbs ae/A (~1.8x) to sugarcane at layby. Following processing of treated RAC, the combined residues were nondetectable (<0.01 ppm) in refined sugar but concentrated in bagasse (processing factor of 6.6x) and molasses (processing factor of 24.4x); bagasse has been deleted from Table 1 of OPPTS 860.1000 as a significant livestock feed item.

The submitted sugarcane processing study is adequate, pending submission of adequate supporting storage stability data for sugarcane molasses. The initial HED review of the subject processing study previously reported that in PP#1F2569, the HAFT was 0.036 ppm (Accession # 070319, Belle Glade, FL, 3 lb ae/A and PHI of 158 days). A more recent sugarcane field study (MRID 44089302) reported a maximum combined HAFT residue of 0.183 ppm from RAC samples harvested 87-173 days following a single layby application of the DGA salt formulations at 2.0 lb ae/A. When the maximum HAFT combined residue level (0.183 ppm) is multiplied by the observed concentration factor for molasses (24.4x), the resulting level is 4.465 ppm which is higher than the currently established tolerance of 2.0 ppm for sugarcane molasses. For the purpose of tolerance reassessment, HED recommends that the tolerance for sugarcane molasses be increased from 2.0 ppm to 5.0 ppm. A tolerance in refined sugar is not necessary.

Wheat

MRID 40663801(DEB Nos. 3968, 3969, 4018, and 4019; 11/4/88; F. Griffith)
MRID 42675901 (DP Barcodes D189039, D189041, and D189043; 4/23/93, L. Cheng)

Established tolerance(s): No tolerance has been established for the combined residues of dicamba and its metabolite (5-OH dicamba) in/on any wheat processed commodities.

Conclusions: Two wheat processing studies with dicamba have been submitted and reviewed. The first study (MRID 40663801) was initially deemed (DEB Nos. 3968, 3969, 4018, and 4019; 11/4/88; F. Griffith) inadequate because the wheat grain samples that were used for processing did not have sufficient residues and, therefore, any concentration of residues (if any) in the processed fractions could not be reliably estimated. The Dicamba SRR, independent of the

11/4/88 review, cited concentration of dicamba residues (2x) in wheat processed fractions (other than flour) and requested registrants to propose a tolerance for wheat processed fractions (other than flour). Based on the results of this study, the Dicamba SRR allowed translation of the wheat processing data to barley and oats.

A second wheat processing study (MRID 42675901) was later submitted and deemed adequate (DP Barcodes D189039, D189041, and D189043; 4/23/93, L. Cheng). The results show that the combined residues of dicamba and 5-OH dicamba did not concentrate in any of the wheat processed fractions. Thus, tolerances in the wheat processed fractions (bran, flour, middlings, shorts, and germs) are not necessary.

Discussion of data: In a wheat processing study (MRID 42675901), the K salt of dicamba (Banvel K+SL) was applied as a spray to wheat when the crop was at the hard dough stage at a rate of either 0.25 lb ai/A (0.25x) or 0.125 lb ai/A (1.25x). The wheat plants were harvested 14 days later, and the harvested grains were processed into bran, middlings, shorts and germ, and patent flour using procedures simulating commercial practices. Only treated samples from the 1.25x rate were analyzed. The treated whole wheat grain (RAC) bore residues of 0.440 ppm for dicamba and 0.034 ppm for 5-OH dicamba. Following processing, residues of the parent and its metabolite were measurable but did not increase in any of the processed fractions. Residues in the processed fractions were: (i) bran (0.436 ppm dicamba + 0.037 ppm 5-OH dicamba); (ii) middlings (0.070 ppm dicamba + <0.01 ppm 5-OH dicamba); (iii) shorts & germ (0.236 ppm dicamba + 0.030 ppm 5-OH dicamba); and (iv) patent flour (0.023 ppm dicamba + <0.01 ppm 5-OH dicamba). Samples were analyzed by a GC method with either EC or HECD detection (Method AM-0691B). The data-collection method is adequate and is well supported by the concurrent method recovery data where control samples of wheat fractions were fortified with dicamba and its plant metabolite, each at 0.01 and 0.1 ppm. Samples were stored frozen for about 4 months before residue analysis. This storage interval is supported by adequate storage stability data

The reregistration requirement for data on the aspirated grain fractions of wheat are discussed under "Aspirated Grain Fractions" section of Miscellaneous Commodities.

860.1650 Submittal of Analytical Reference Standards

Analytical standards for dicamba acid, DMA salt of dicamba, and Na salt of dicamba are currently available (as of 5/6/2005) in the National Pesticide Standards Repository; however, no standards are available for 5-OH dicamba and DCSA. Analytical reference standards of dicamba and its regulated metabolites must be supplied, and supplies replenished as requested by the Repository. The reference standards should be sent to the Analytical Chemistry Lab, which is located at Fort Meade, to the attention of either Theresa Cole or Frederic Siegelman at the following address:

USEPA
National Pesticide Standards Repository/Analytical Chemistry Branch/OPP
701 Mapes Road

Fort George G. Meade, MD 20755-5350
(Note that the mail will be returned if the extended zip code is not used.)

860.1850 Confined Accumulation in Rotational Crops

MRID 41972001 (DP Barcode D197629, 2/16/96, L. Cheng)
MRID 43698601 (DP Barcodes D228694 and D239967, 6/25/98, S. Chun)

Two confined rotational crop studies with dicamba are available.

The first study (MRID 41972001) was deemed inadequate because the test substance, uniformly ring-labeled [^{14}C]dicamba acid, was applied at only 0.5 lb ae/A which is 0.5x the maximum rate of 1.0 lb ae/A for cereal grains or 0.25x the maximum rate of 2.0 lb ae/A for pasture and rangeland grasses: see Use Closure Memorandum for Dicamba In Table 4. The possibility of obtaining rotational crop commodity samples with sufficient radioactive residues (e.g., at the 131- and 369-day plantback interval) may have been compromised as a result of the <1x application rate. Furthermore, the reported results of the characterization and identification of radioactive residues, using samples from the 32-day plantback interval, are inconclusive since details and quantitative raw data (e.g., material balance to account for the radioactivity in extractable and non-extractable fractions as well as sample chromatograms) were not provided. The Agency review of this study required a new confined rotational crop study since upgrading the study by further analyses on stored samples is not feasible because the study was initiated in 1986.

A new confined rotational crop study (MRID 43698601) was subsequently submitted. The HED review of this study noted two major deficiencies: (i) the test material was applied to growing corn plants instead of bare ground as specified in OPPTS Guideline 860.1850; and (ii) carrot tops were not sampled. The first deviation would be expected to effect the quantitative aspects of the study since the plants would prevent an unknown percentage of the test substance from reaching the soil; i.e., the actual application rate is unknown. Carrot tops should have been sampled as they are a representative of the root crop group and there are some members of this which have edible foliage. However, the HED review concluded that the study need not be repeated because the TRR values at the plantback interval of 120 days, which the registrant wishes to support, were very low and were found to be associated with natural products. It is, thus, unlikely that the addition of the test material intercepted by the corn plants would result in significant residues of metabolites or that residues would be significantly different in carrot tops from those in the other RACs. A brief summary of the reviewed confined rotational crop study is presented below.

Uniformly ring labeled [^{14}C]dicamba was applied to corn plants at 0.75 lb ai/A when the plants were at the two- to three-leaf stage. At 30 and 120 days after treatment (DAT), corn was removed prior to planting barley, carrots, and collards. For the 365 DAT plantings, corn was harvested at maturity (160 DAT). At 365 DAT, soybeans were planted. The crops were grown to maturity and harvested. The raw agricultural commodities (RACs) harvested for radiocarbon residue determination at 30, 120, and 365 DAT were barley forage, grain, and straw; carrot roots and collard greens. Data from carrot tops were not included despite EPA's requirement of analysis of the aerial and root portions of root crops. RACs harvested for radioactive residue determination at 365 DAT only were soybean forage, hay, and seed. All RACs were analyzed within 4.5 months of harvest, obviating the storage stability data requirement. Total radioactive residue levels in plant samples are listed in Table 7.

Table 7. Total Radioactive Residue of [^{14}C]Dicamba in Rotational Crops (MRID 43698601).

RAC	TRR in Rotational Crop RACs in ppm[1]		
	30 DAT	120 DAT	365 DAT
Barley forage	4.741 (80)	0.036 (177)	BLD[2] (419)
Barley straw	9.487 (129)	0.027 (259)	0.008 (463)
Barley grain	0.272 (129)	0.022 (259)	0.009 (463)
Collard greens	0.026 (126)	0.007 (209)	BLD[2] (434)
Carrot roots	1.022 (171)	0.005 (260)	BLD[2] (463)
Soybean forage	NA[3]	NA[3]	0.006 (497)
Soybean hay	NA[3]	NA[3]	BLD[2] (518)
Soybean seed	NA[3]	NA[3]	BLD[2] (583)

[1] In parenthesis is the number of days from dicamba treatment to harvest for the RAC/plantback interval combination indicated.
[2] Below limit of detection.
[3] Not applicable.

Because TRRs as high as 9.5 ppm were found in the 30-DAT plantback interval samples, the registrant is requesting a 120-DAT plantback interval without tolerances. Table 7 shows that the TRRs for all rotational crop RACs planted 120 and 365 DAT were ≤0.036 and <0.01 ppm, respectively. Ordinarily, when residues are <0.01 ppm, no further characterization of the residue is required. Hence, no characterization is needed for any of the 365 DAT samples or the 120-DAT collard green or carrot root samples. However the TRRs for the barley grain, forage, and hay were all > 0.01 ppm, requiring determination of the composition of the TRR. This was accomplished by subjecting samples to acetonitrile extraction (to obtain extractable residues) and acid/base hydrolysis steps (to obtain bound residues). The results of the extraction profile for 120-DAT barley forage, grain, and straw indicate that approximately 35-52% of TRRs are associated with natural plant constituents (lignin and cellulose).

860.1900 Field Accumulation in Rotational Crops

Limited and/or extensive field accumulation studies with dicamba need not be conducted and rotational crop tolerances need not be established *provided* the registrants are willing to amend all dicamba labels with food/feed use claims to specify a 120-day plantback interval when dicamba is applied at a maximum seasonal rate of 0.75 lb ae/A or less. At application rates of 0.75-2.0 lb ae/A, the labels should specify that only crops with established tolerances can be rotated.

The results of the available confined rotational crop study showed that at a plantback interval of 120 days, the total radioactive residues were <0.01 ppm in/on samples of collard greens (a representative of leafy vegetables) and carrots (a representative of root crops) but were >0.01 ppm in the matrices of barley (a representative of small grains). Residue characterization of barley matrices from the 120-day rotation showed that a good percentage of TRR was associated with natural plant constituents.

TOLERANCE REASSESSMENT SUMMARY

The established tolerances for dicamba are listed in 40 CFR §180.227. There are three dicamba tolerance expressions. Under 40 CFR §180.227 (a)(1), the tolerances are expressed in terms of the combined residues of the herbicide dicamba (3,6-dichloro-o-anisic acid) and its metabolite 3,6-dichloro-5-hydroxy-o-anisic acid. The tolerances listed in 40 CFR §180.227 (a)(2) are expressed in terms of the combined residues of dicamba and its metabolite 3,6-dichloro-2-hydroxybenzoic acid. Finally, the tolerances listed in 40 CFR §180.227 (a)(3) are expressed in terms of the combined residues of dicamba and its metabolites 3,6-dichloro-5-hydroxy-o-anisic acid and 3,6-dichloro-2-hydroxybenzoic acid.

The results of plant and animal metabolism studies suggest that the various tolerance expressions for dicamba are appropriate. The results of a confined rotational crop study indicate that tolerances need not be established for rotational crops pending label revisions to specify appropriate rotational crop restrictions.

A summary of the tolerance reassessment and recommended modifications in commodity definitions for dicamba is presented in Table 8.

Tolerances Established Under CFR §180.227 (a)(1)

Pending label revisions and/or adjustment of tolerances, there are adequate residue data to reassess the tolerances for: barley, grain, hay, and straw; corn, field, grain, forage, and stover; grass forage and hay; wheat grain, straw, forage and hay; and sorghum grain, forage, and stover.

The submitted data for several commodities do not support the established tolerances because they do not reflect the maximum use rates listed in Dicamba Master Use Profile. To fulfill reregistration requirements, the registrant are required to submit additional data. In lieu of submitting additional data, the registrants are given the option to rely on the available data provided they revise their product labels for consistency with the reviewed data.

HED will allow the translation of available/requested data from some crop commodities to agronomically related commodities with identical uses. Where this situation exists, any HED recommendations with regards to label revision and tolerance reassessment should apply to both crop commodities. The following translations have been made in this Residue Chemistry Chapter: (i) data from field corn grain and stover may be translated to pop corn grain and stover; (ii) data from wheat grain may be translated to proso millet grain and rye grain; (iii) data from wheat forage, hay, and straw may be translated to oat forage, hay, and straw; and (iv) data from wheat straw may be translated to proso millet straw.

Pending submission of supporting storage stability data, an acceptable sugarcane processing study is available to reassess the established tolerance for sugarcane molasses. When the maximum HAFT combined residue level (0.183 ppm) of the RAC is multiplied by the observed concentration factor for sugarcane molasses (24.4x), the resulting level is 4.465 ppm which is higher than the current tolerance of 2.0 ppm. Based on these data, HED recommends that the tolerance for sugarcane molasses be increased from 2.0 ppm to 5.0 ppm, toxicological considerations permitting.

The Agency no longer considers sugarcane forage and fodder to be significant livestock feed items, and these items have been deleted from Table 1 of OPPTS 860.1000. Therefore, the respective tolerances should be revoked.

The tolerance for cottonseed meal is not needed because the recommended tolerance level for cottonseed is greater than the highest average field trial level (HAFT) multiplied by the concentration factor in meal.

The generic "corn, forage" tolerance should be revoked since a separate tolerance for field corn forage is established. The generic "corn, stover" tolerance should be revoked since separate tolerances are established for field corn stover and pop corn stover. The generic "corn, grain" tolerance should be split into: "corn, field, grain" and "corn, pop, grain".

<u>Tolerances Needed Under CFR §180.227 (a)(1)</u>

Tolerances are needed for proso millet forage and hay. The available/requested data for wheat forage and hay may be translated to proso millet forage and hay.

Tolerances are needed for rye grain, forage, and straw. The available/requested data for wheat grain, forage, and straw may be translated to rye grain, forage, and straw.

Tolerances are needed for cotton gin-by-products, but additional information regarding the conduct of the field trials.

<u>Tolerances Established Under CFR §180.227 (a)(2)</u>

Pending label revisions and/or adjustment of tolerance, there are adequate data to reassess the established tolerance for asparagus.

Adequate data are available to reassess the established ruminant tolerances.

<u>Tolerances Established Under CFR §180.227 (a)(3)</u>

There are adequate data to reassess the tolerances for soybean seed and soybean hulls.

An acceptable soybean processing study is available to reassess the established tolerance for soybean hulls. When the HAFT combined residue level (7.44 ppm) for the RAC is multiplied by the observed concentration factor for soybean hulls (3.8x), the resulting level is 28.272 ppm which suggests that the existing tolerance of 13.0 ppm needs an upward adjustment. Based on these data, HED recommends that the tolerance for soybean hulls be increased from 13.0 ppm to 30.0 ppm.

There are adequate residue data on the aspirated grain fractions of sorghum, soybean, and wheat and may be translated to corn.

Tolerances That May Be Needed Under CFR §180.227 (a)(3)
It is the current Agency policy to allow label restrictions on the feeding/grazing of livestock animals on soybean forage and hay, thus, precluding the need for residue data and tolerances for these soybean commodities. HED defers to RD for verifying whether such restrictions exist on product labels. If such restrictions appear on the labels, then residue data and tolerances for soybean forage and hay are not necessary. If no such restrictions appear on the labels, then the registrants are required to propose tolerances for soybean forage and hay; based on the available data, a tolerance level of 0.1 ppm would be appropriate for each soybean commodity. Concomitant with these tolerance proposals, the registrants are required to propose a maximum seasonal rate of 0.5 lb ae/A for preplant application on soybean grown for forage and hay only.

Pending Tolerance Petition:

PP#6E06209: Interregional Research Project No. 4 (IR-4) has submitted a petition, on behalf of the Agricultural Experiment Stations of MN, ND and WI, proposing the following permanent tolerances for the combined residues of the herbicide dicamba and its 5-hydroxy (5-OH) metabolite (3,6-dichloro–5-hydroxy-o-anisic acid) in/on: sweet corn forage at 1.0 ppm, fresh sweet corn at 0.1 ppm, and sweet corn stover at 1.0 ppm. HED's evaluation of residue data and analytical methods (DP Barcode D275611, 7/26/2001, G. Kramer) concluded that additional field residue trials need to be conducted and a revised Section F must be submitted before a favorable recommendation can be made.

Codex/International Harmonization

No Codex MRLs have been established for dicamba; therefore, issues of compatibility between Codex MRLs and U.S. tolerances do not exist. Compatibility cannot be achieved with the Canadian negligible residue limits or with Mexican MRLs because these levels are expressed in terms of parent compound only.

Table 8. Tolerance Reassessment Summary for Dicamba.

Commodity	Current Tolerance (ppm)	Reassessed Tolerance (ppm)	Comments/ *Correct commodity definition*
Dicamba Tolerances Listed Under 40 CFR §180.227 (a)(1) [Expressed in terms of the combined residues of dicamba and its metabolite 3,6-dichloro-5-hydroxy-*o*-anisic acid]			
Barley, grain	6.0	6.0	
Barley, hay	2.0	2.0	
Barley, straw	15.0	15.0	
Corn, field, forage	3.0	3.0	The combined residues ranged from <0.01 to 2.27 ppm in/on field corn forage harvested 39-71 days following the last of three sequential treatments for a total of 2.75 lb ae/A. The combined residues ranged from <0.01 to 2.45 ppm in/on field corn fodder harvested 66-123 days following same sequential treatments.
Corn, field, stover	3.0	3.0	
Corn, forage	0.5	Revoke	The generic "corn, forage" tolerance should be revoked since a separate tolerance for field corn forage is established.
Corn, grain	0.5	0.1	The combined residues ranged from <0.01 to 0.015 ppm in/on field corn grain samples harvested 69-123 days following the last of three sequential treatments for a total of 2.75 lb ae/A. The generic "corn, grain" tolerance should be split into: "corn, field, grain"; and "corn, pop, grain".
Corn, pop, stover,	3.0	3.0	HED will allow the translation of available data for field corn stover to pop corn stover. Any label revision for field corn should also be made for pop corn. Concurrently, any adjustment to the field corn stover tolerance should also be applied as necessary to the pop corn stover tolerance.
Corn, stover	0.5	Revoke	The generic "corn, stover" tolerance should be revoked since separate tolerances are established for field corn stover and pop corn stover.
Cotton, undelinted seed	5.0	0.2 ppm	The maximum residue detected in cottonseed from a single application at 0.5 lb ai/A 14 days prior to planting was 0.05 ppm of the 5-OH metabolite in only one field trial. The reassessed tolerance is based on twice the combined LOQs of the parent and metabolite. Residues in meal concentrate 1.9x. The recommended tolerance level for cottonseed is greater than the highest average field trial level (HAFT) multiplied by the concentration factor in meal, so a separate tolerance for meal is not needed.
Cotton, meal	5.0	Revoke	

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Table 8. Tolerance Reassessment Summary for Dicamba.

Commodity	Current Tolerance (ppm)	Reassessed Tolerance (ppm)	Comments/ *Correct commodity definition*
Crop Group 17 (grass forage, fodder, and hay)			The combined residues ranged 66-358 ppm in/on grass forage samples harvested immediately (0-day) following a single application at 2.0 lb ae/A (1x). The combined residues ranged 25-201 ppm in/on grass hay samples harvested 7 days following a single application 1x. Based on these data, HED is reassessing the grass forage tolerance at 400 ppm and the grass hay tolerance at 250 ppm. Concomitant with the reassessment of these tolerances, HED is requesting RD to verify that all dicamba labels specify a 0-day PHI/PGI for grass forage and a 7-day PHI for grass hay when applied at a maximum of 2.0 lb ae/A.
- Grass forage	125.0	400	
- Grass hay	200.0	250	
Millet, proso, grain	0.5	2.0	HED will allow the translation of available/requested data for wheat grain and straw to proso millet grain and straw since the Dicamba Master Use Profile indicates that the application rate for wheat is higher than millet.
Millet, proso, straw	0.5	TBD	
Oat, grain	0.5	TBD	HED will allow the translation of available/requested data for wheat grain to oat grain since the Dicamba Master Use Profile indicates that the application rate of the two crops is identical.
Oat, forage	80.0	90	HED will allow the translation of available/requested data for wheat forage, hay, and straw to oat forage, hay, and straw since the Dicamba Master Use Profile indicates that the application rate of the two crops is identical.
Oat, hay	20.0	40	
Oat, straw	0.5	30	
Sorghum, grain	3.0	4.0	The maximum combined residues were 2.73 ppm (MRID 43245203) and 3.164 ppm (MRID 44089306) in/on sorghum grain harvested 30-42 days following sequential treatments for a total rate of 0.5 lb ae/A (1x the maximum rate listed in the Dicamba Master Use Profile). These data suggest that the established tolerance for sorghum grain may be too low. Based on the reviewed data, HED is recommending a tolerance level of 4.0 ppm for sorghum grain concomitant with label revision to specify a 30-day PHI.

Table 8. Tolerance Reassessment Summary for Dicamba.

Commodity	Current Tolerance (ppm)	Reassessed Tolerance (ppm)	Comments/ *Correct commodity definition*
Sorghum, forage	3.0	0.5	The maximum combined residues were 0.46 ppm (MRID 43245203) and 0.350 ppm (MRID 44089306) in/on sorghum <u>forage</u> samples harvested 20-72 days following a single postemergence application at 0.25 lb ae/A (0.5x the seasonal rate listed in the Dicamba Master Use Profile). The maximum combined residues were 8.22 ppm (MRID 43245203) and 4.29 ppm (MRID 44089306) in/on sorghum <u>fodder</u> (stover) samples collected at PHIs of 30-42 days following the last of two applications for a total rate of 0.5 lb ae/A (1x). These data suggest that the established tolerance for sorghum forage may be too high and the tolerance for fodder too low. Based on these data, HED is recommending tolerance levels of 0.5 ppm for sorghum forage and 10.0 ppm for sorghum stover concomitant with the following recommended label revisions: (i) a 20-day PHI and a maximum single/seasonal rate of 0.25 lb ae/A for sorghum forage; and (ii) a 30-day PHI for sorghum fodder (stover) at a maximum seasonal rate of 0.5 lb ae/A.
Sorghum, grain, stover	3.0	10	
Sugarcane, cane	0.1	TBD [1]	The available data do not support the maximum seasonal single/yearly rate of 2.8 lb ae/A that is listed in the Dicamba Master Use Profile because the sugarcane trials were conducted at an application rate of 2.0 lb ae/A. The maximum combined residues were 0.202 ppm in/on sugarcane harvested 87-173 days following a single layby application at 2.0 lb ae/A. The registrants are required to submit additional data on sugarcane reflecting a maximum single/yearly rate of 2.8 lb ae/A. Alternatively, the registrants may rely on the available data provided they are willing to revise their product labels for consistency with the reviewed data. If the registrants elect to choose the latter option, then they will be required to revise product labels to specify a maximum seasonal rate of 2.0 lb ae/A and an 87-day PHI for sugarcane. Based on the reviewed data, the existing tolerance of 0.1 ppm for sugarcane is too low, and HED is recommending that it be reassessed at 0.3 ppm *if* the registrants elect to revise product labels as detailed above.
Sugarcane, fodder	0.1	Revoke	These items are no longer regulated and have been removed from Table 1 of OPPTS 860.1000.
Sugarcane, forage	0.1	Revoke	

Table 8. Tolerance Reassessment Summary for Dicamba.			
Commodity	Current Tolerance (ppm)	Reassessed Tolerance (ppm)	Comments/ *Correct commodity definition*
Sugarcane, molasses	2.0	5.0	When the maximum HAFT combined residue level (0.183 ppm) of the RAC is multiplied by the observed concentration factor for sugarcane molasses (24.4x), the resulting level is 4.465 ppm which is higher than the current tolerance of 2.0 ppm. Based on these data, HED recommends that the tolerance for sugarcane molasses be increased from 2.0 ppm to 5.0 ppm, pending submission of supporting storage stability data.
Wheat, forage	80.0	90	The available data indicate that the maximum combined residues of dicamba and 5-OH dicamba were 86 ppm in/on wheat forage samples harvested immediately (0-day PHI) following a single application of dicamba at 0.5 lb ai/A.
Wheat, grain	2.0	2.0	The combined residues were <0.01 to 0.15 ppm in/on samples of wheat grain harvested 63-125 days following one spring broadcast application at 0.25 lb ae/A. The combined residues were 0.039 to 1.4 ppm in/on grain samples harvested 6-12 days following the last of two treatments for a total of 0.5 lb ae/A.
Wheat, hay	20.0	40	The available data indicate that the maximum combined residues of dicamba and 5-OH dicamba were 34 ppm from in/on wheat hay harvested 14 days following a single application of dicamba at 0.5 lb ai/A.
Wheat, straw	30.0	30	The combined residues were 0.011 to 0.97 ppm in/on samples of wheat straw harvested 63-125 days following one spring broadcast application at 0.25 lb ae/A. The combined residues were 0.13 to 26 ppm in/on straw samples harvested 6-12 days following the last of two treatments for a total of 0.5 lb ae/A.
Dicamba Tolerances Needed Under 40 CFR §180.227(a)(1)			
Millet, proso, forage	None	90	HED will allow the translation of available/requested data for wheat forage and hay to proso millet forage and hay since the Dicamba Master Use Profile indicates that the application rate for wheat is slightly higher than millet.
Millet, proso, hay	None	40	
Rye, grain	None	2.0	HED will allow the translation of available/requested data for wheat grain, forage, and straw to rye grain, forage, and straw since the Dicamba Master Use Profile indicates that the yearly application rate of the two crops is identical.
Rye, forage	None	90	
Rye, straw	None	40	
Dicamba Tolerances Listed in 40 CFR §180.227 (a)(2) **[Expressed in terms of the combined residues of dicamba and its metabolite 3,6-dichloro-2-hydroxybenzoic acid]**			

Table 8. Tolerance Reassessment Summary for Dicamba.			
Commodity	Current Tolerance (ppm)	Reassessed Tolerance (ppm)	Comments/ *Correct commodity definition*
Asparagus	4.0	4.0	Th combined residues ranged 0.28-3.29 ppm in/on asparagus samples harvested 24 hours following a single application at 1x the maximum rate listed in the Dicamba Master Use Profile. These data support the currently established tolerance of 4.0 ppm on asparagus pending verification by RD that the label PHI for asparagus is 24 hours or 1 day.
Cattle, fat	0.2	0.3	Reassessed values are based on a new ruminant feeding study.
Cattle, kidney	1.5	25	Reassessed values are based on a new ruminant feeding study.
Cattle, liver	1.5	Revoke	Residues in liver will be covered by redefined meat by-products tolerance.
Cattle, meat byproducts	0.2	3.0	*Cattle, meat by-products, except kidney.* Reassessed values are based on a new ruminant feeding study currently under review.
Cattle, meat	0.2	0.25	Reassessed values are based on a new ruminant feeding study
Goat, fat	0.2	0.3	Reassessed values are based on a new ruminant feeding study
Goat, kidney	1.5	25	Reassessed values are based on a new ruminant feeding study
Goat, liver	1.5	Revoke	Residues in liver will be covered by redefined meat by-products tolerance.
Goat, meat byproducts	0.2	3.0	*Goat, meat by-products, except kidney*
Goat, meat	0.2	0.25	Reassessed values are based on a new ruminant feeding study
Hog, fat	0.2	0.3	Reassessed values are based on a new ruminant feeding study
Hog, kidney	1.5	25	Reassessed values are based on a new ruminant feeding study
Hog, liver	1.5	Revoke	Residues in liver will be covered by redefined meat by-products tolerance.
Hog, meat byproducts	0.2	3.0	*Hog, meat by-products, except kidney*
Hog, meat	0.2	0.25	Reassessed values are based on a new ruminant feeding study
Horse, fat	0.2	0.3	Reassessed values are based on a new ruminant feeding study
Horse, kidney	1.5	25	Reassessed values are based on a new ruminant feeding study
Horse, liver	1.5	Revoke	Residues in liver will be covered by redefined meat by-products tolerance.
Horse, meat byproducts	0.2	3.0	*Horse, meat by-products, except kidney* Reassessed values are based on a new ruminant feeding study currently under review.

Table 8. Tolerance Reassessment Summary for Dicamba.			
Commodity	Current Tolerance (ppm)	Reassessed Tolerance (ppm)	Comments/ *Correct commodity definition*
Horse, meat	0.2	0.25	Reassessed values are based on a new ruminant feeding study
Milk	0.3	0.2	Reassessed values are based on a new ruminant feeding study
Sheep, fat	0.2	0.3	Reassessed values are based on a new ruminant feeding study
Sheep, kidney	1.5	25	Reassessed values are based on a new ruminant feeding study
Sheep, liver	1.5	Revoke	Residues in liver will be covered by redefined meat by-products tolerance.
Sheep, meat byproducts	0.2	3.0	*Sheep, meat by-products, except kidney* Reassessed values are based on a new ruminant feeding study currently under review.
Sheep, meat	0.2	0.25	Reassessed values are based on a new ruminant feeding study
Dicamba Tolerances Under 40 CFR §180.227(a)(3) [Expressed in terms of the combined residues of dicamba and its metabolites 3,6-dichloro-5-hydroxy-*o*-anisic acid and 3,6-dichloro-2-hydroxybenzoic acid]			
Grain, aspirated grain fractions	5100	1000	There are adequate residue data on the aspirated grain fractions of sorghum, soybean, and wheat, and can be translated to corn.
Soybean, hulls	13.0	30.0	When the maximum HAFT combined residue level (7.44 ppm) of the RAC is multiplied by the observed concentration factor for soybean hulls (3.8x), the resulting level is 28.272 ppm which suggests that the existing tolerance of 13.0 ppm is too low. HED recommends that the tolerance for soybean hulls be increased from 13.0 ppm to 30.0 ppm.
Soybean, seed	10.0	10.0	The highest total residues were 8.13 ppm in/on samples of soybean seed harvested 6-8 days following treatments at 1.25x the maximum rate listed in the Dicamba Master Use Profile.
Dicamba Tolerances That May Be Needed Under 40 CFR §180.227(a)(3)			

Table 8. Tolerance Reassessment Summary for Dicamba.

<table>
<tr><th>Commodity</th><th>Current Tolerance (ppm)</th><th>Reassessed Tolerance (ppm)</th><th>Comments/
Correct commodity definition</th></tr>
<tr><td>Soybean, forage</td><td>None</td><td>TBD</td><td rowspan="2">It is the current Agency policy to allow label restrictions on the feeding/grazing of livestock animals on soybean forage and hay, thus, precluding the need for residue data and tolerances. HED defers to RD for verifying whether such restrictions exist on product labels. If such restrictions appear on the labels, then residue data and tolerances for soybean forage and hay are not necessary. If no such restrictions appear on the labels, then the registrants are required to propose tolerances for soybean forage and hay; based on the available data, a tolerance level of 0.1 ppm would be appropriate for each soybean commodity. Concomitant with these tolerance proposals, the registrants are required to propose a maximum seasonal rate of 0.5 lb ae/A for preplant application on soybean grown for forage and hay.</td></tr>
<tr><td>Soybean, hay</td><td>None</td><td>TBD</td></tr>
</table>

[1] TBD = To be determined. Additional data/information are required for tolerance reassessment.

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44089306 Guirguis, M. (1996) Crop Residue Study with Dicamba Formulation on Sorghum: Final Report: (Data submitted as alternate to Craven Laboratories generated data): Lab Project Number: 480068/148: DP-302998: 110/95/01. Unpublished study prepared by Minnesota Valley Testing Lab. 284 p.

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46668101; Formanski, L. J. (1996) "Stability of Dicamba and 3,6-Dichlorosalicylic Acid in Stored Frozen Beef Tissues and Milk". Lab Project Number: 480068. Report No. 151. Study No. DP-304489. Unpublished study prepared by Sandoz Agro, Inc. 275 pages.

AGENCY MEMORANDA RELEVANT TO THIS RESIDUE CHAPTER AND TOLERANCE REASSESSMENT

Table 9. Agency Memoranda Citations.

Date	DP Barcode	CB No.	From	To	MRID Nos.	Subject
11/29/05	D322842	None	C. Olinger	K. Tyler	44089303, 46668101	
11/24/05	D320555, D320563, and D320570	None	C. Olinger	K. Tyler	41187301, 44891302, and 45196801	Reregistration of Dicamba: Wheat Forage/Hay and Cotton Gin By-Product Crop Field Trials; Corn Processing Study
12/05	D320550-D320551	None	C. Olinger	K. Tyler	44089302, 44089306	Dicamba. Case 0065. PC Code 029801. Residue Data in Sorghum and Sugarcane.
3/10/05	D312086	None	G. Kramer	D. Kenny/ J. Miller	None	Review of Label Amendment for Dicamba + 2,4-D (Outlaw™, EPA Registration #42750-68).
7/26/01	D275611	None	G. Kramer	S. Brothers/ R. Forrest	45154001	PP# 6E06209. Dicamba (Distinct®, EPA Reg #7969-150) on Sweet Corn. Evaluation of Residue Data and Analytical Methods.
10/13/98	D249098	None	W. Donovan	J. Miller/ E. Wilson	None	PP#s 6F4604 and 4F3041 - Dicamba (Clarity® Herbicide) on Asparagus, Corn, Cotton, Grass Forage and Hay, and Wheat Forage and Hay. Preharvest Use on Wheat, Barley, and Soybean. Amendment of 31-Aug-1998.
7/16/98	D228703	None	S. Chun	J. Miller/ E. Wilson	43866601, 44089303, 44089304, 44089305, 44089307	PP# 4F3041- Dicamba (Banvel®, Clarity®, IPA Salt of Dicamba, Banvel® SGF) Preharvest Use on Wheat, Barley, Corn, and Soybeans; Preplant burndown use on Soybeans. Amendment of 9/9/97.
6/25/98	D228694, D239967	None	S. Chun	J. Miller/ E. Wilson	43698601	PP# 6F4604- Dicamba (Banvel®, Clarity®, IPA Salt of Dicamba, Banvel® SGF) on Cotton, Asparagus, Grass Forage and Hay, and Wheat Forage and Hay. Amendment of 9/9/97.
7/14/97	D204488, D204809, D209229	13882, 13948, 14695	L. Cheng	K. Whitby	43245203, 43274501, 43245206, 43425803, 43245204, 43245205	Dicamba. Case 0065. PC Code 029801. Residue Data in Sorghum, Wheat, Asparagus, and Sorghum and Sugarcane Processed Fractions.

Table 9. Agency Memoranda Citations.						
Date	**DP Barcode**	**CB No.**	**From**	**To**	**MRID Nos.**	**Subject**
1/21/97	D232478	17705	J. Stokes	D. McCall	None	PP#6F4604. Dicamba. Petition Method Validation Results.
7/29/96	D223283, D223292, D223300, D223311, D223380, D223383, D223361, D223363, D223316, D223320, D223373, D223374, D223355, D223356	None	S. Knizner, W. Dykstra, and C. Lewis	J. Whitehurst	43814101, 43814102, 43814103, 43814104	Dicamba Amendment to PP#4F3041/FAP#4H5428 and PP#4G3061 for Preharvest Use of Dicamba on Wheat, Barley, and Soybeans. Withdrawal of PP#4G3061 - Preplant Burndown Use of Dicamba in Soybeans.
6/27/96	D227359	None	F. Griffith	D. Marlow	42883201, 43814002	PP# 6F4604 - Dicamba (Banval®) on Cotton, Asparagus, Grass Forage and Hay, and Wheat Forage and Hay. Tolerance Method Validation (TMV) Request.
6/24/96	D226526	17271	D. Miller	P. Deschamp	None	Dicamba (029801). Registrant Response to Ruminant and Hen Metabolism Studies. GDLN 171-4b.
5/2/96	D220430, D220469, D220471, D220473	16431, 16432, 16433, 16434	F. Griffith	D. McCall	42283201, 43814001, 43814002, 43274501, 43370701	PP# 6F4604 - Dicamba (Banval®) on Cotton, Asparagus, Grass Forage and Hay, and Wheat Forage and Hay.
3/11/96	D207649	14378	L. Cheng	J. Mitchell	43370701	Dicamba. Case 0065. Residue Data in Grass Forage and Hay.
3/7/96	D204482	13874	L. Cheng	J. Mitchell	43245201 and 43245202	Dicamba. Case No. 0065. Ruminant and Hen Metabolism Data for GLN 171-4b.
2/16/96	D197629	12947	L. Cheng	J. Mitchell	41972001	Dicamba. Case 0065. Confined Rotational Crop Study.

Table 9. Agency Memoranda Citations.

Date	DP Barcode	CB No.	From	To	MRID Nos.	Subject
7/12/94	D204754	13923	S. Funk	W. Waldrop/ J. Mitchell	None	Dicamba (List A, Case No. 0065, Chemical No. 029801). Sandoz Proposal for the Replacement of Craven Data.
1/31/94	None	None	M. Metzger	J. Mitchell	None	Dicamba. Meeting with Registrant on 1/12/94, phone call of 1/19/94. Field Trial Requirements.
12/14/93	D194776	12482	D. Miller	J. Mitchell	42883201	Dicamba. Independent Method Validation.
9/13/93	D193993, D193995	12358, 12359	D. Davis	R. Taylor/ V. Walters/ A. Kocialski	None	PP#3F2794/PP#4H5439. Dicamba in/on Cotton (Preplant Application).
5/21/93	D189821	11702	D. Davis	R. Taylor/ V. Walters	None	PP#3F02794. Dicamba in/on Cotton (Between Crop Application). Amendment to Permanent Tolerance Petition to Replace DMA Salt of Dicamba with Sodium Salt.
	D189823	11703	D. Davis	R. Taylor/ V. Walters	None	PP#3F02794. Dicamba in/on Cotton (Between Crop Application). Amendment to FAT Petition to Replace DMA Salt of Dicamba with Sodium Salt.
	D189825	11704	D. Davis	R. Taylor/ V. Walters	None	ID# 055947-00028. Banvel SGF® Herbicide. Label Amendment.
4/23/93	D189039, D189041, D189043	11542	L. Cheng	R. Taylor/ V. Walters and Toxicology Branch	42675901	Dicamba (SRR) Registration Standard: Response. PP#4F3041/FAP#4H5428. Dicamba (ID #55947-38; Potassium Salt) on Grass and Grains. Amendment Wheat Processing Study.
1/17/92	D169036	8617	R. Lascola	R. Taylor	None	Dicamba (Banvel). Impact of Craven Laboratories Analytical Data on Registrations.
9/23/91	D167962	8517	M. Metzger	S. Stanton	None	91-MS-11. Dicamba on Cotton. (EPA Reg. No. 55947-1).
7/26/90	None	6712	S. Funk	R. Taylor/ V. Walters	41387001	Amended Registration Request for Banvel Herbicide (Dicamba DMA Salt); Petitioner's Response to Deficiencies. I.D. No. 55947-1. Record No. 265171.

Table 9. Agency Memoranda Citations.

Date	DP Barcode	CB No.	From	To	MRID Nos.	Subject
6/30/89	None	None	R. Schmitt	R. Engler/ L. Rossi	Refer to the Residue Chemistry Chapter	Dicamba (SRR) Registration Standard.
5/18/89	None	4424 and 4425	E. Haeberer	R. Taylor and Toxicology Branch	40642801 and 40547911	PP#3F2794/FAP# 4H5439; Dicamba in/on Cotton, Supplemental Submission of May 27, 1988; Cotton Metabolism Study, Storage Stability Study.
11/4/88	None	3968, 3969, 4018, 4019	F. Griffith	R. Taylor and Toxicology Branch	40663801	PP#4F3041/FAP#4H5428 - Dicamba on Grass and Grains. Evaluation of June 14, 1988, Amendment.
8/12/83	None	None	C. Trichilo	A. Rispin/ R. Taylor	Refer to the Residue Chemistry Chapter	Dicamba Registration Standard.
7/28/81	None	None	A. Rathman	R. Taylor	Refer to the Residue Chemistry Chapter	PP#1G2502, FAP#1H5306. Dicamba on Cotton. Evaluation of Analytical Methods and Residue Data.

13544

R119415

Chemical: Dicamba
Benzoic acid, 3,6-dichloro-2-methoxy-, compd with N-methylmethanamine (1:1)
Benzoic acid, 3,6-dichloro-2-methoxy-, sodium salt
Benzoic acid, 3,6-dichloro-2-methoxy-, compd with 2-(2-aminoethoxy)ethanol (1:1)
Benzoic acid, 3,6-dichloro-2-methoxy-, compd with 2-propanamine (1:1)
Benzoic acid, 3,6-dichloro-2-methoxy-, potassium salt

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